

To Observe Implementation of American Diabetes Association (ADA) Guidelines for Care of Type 2 Diabetics at Peripheral Diabetes Clinics (PDCs) in Pakistan

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*This work is dedicated to
My beloved Amma and Abba (parents)*

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ABSTRACT

OBJECTIVE — To observe the implementation of American Diabetes Association (ADA) guidelines for care of type 2 diabetics at Peripheral Diabetes Clinics (PDCs) in Karachi, Pakistan.

RESEARCH DESIGN AND METHODS — The study was performed using a retrospective medical chart review of 691 type 2 diabetic patients 20 years of age and older. All of these patients had a definitive diagnosis of type 2 diabetes and records were documented on their first visit. Four peripheral diabetes clinics in four townships of Karachi district which were in operation between 1 Jan 2005 to 29 Dec 2006 were selected.

RESULTS — A total of 691 patients (332 males and 359 females) with type 2 diabetes had a mean age of 50.94 ± 10.4 years. Mean BMI was 26.6 ± 4.77 kg/m² and 60% of these patients had a positive family history of diabetes. Comorbidities were largely present, 84.6% had hyperlipidemia, 59% were hypertensive, 31.3% had retinopathy, 22.6% had nephropathy and 18.6% had peripheral neuropathy.

On their first visit 86% had their blood pressure measured, 56% patients had serum creatinine measured, 45% had HbA1c measured, 31% patients had dilated eye examinations, and 25% had urine albumin screening. Of these patients, 44% had lower leg examination and 2% patients were suffering from diabetic foot ulcer.

Mean systolic blood pressure (SBP) was 138 ± 19.8 mm Hg, mean diastolic blood pressure (DBP) was 85.58 ± 9.6 mmHg. Mean fasting blood glucose levels was 194.32 ± 70.59 mg/dl, random blood glucose levels was 278.86 ± 100.75 mg/dl and mean HbA1c levels was $9.13 \pm 1.6\%$. Mean cholesterol levels was 194.15 ± 42.79 mg/dl, mean triglyceride levels was 224 ± 118.12 mg/dl, HDL cholesterol levels was 39.16 ± 7.1 mg/dl and LDL cholesterol levels was 117.62 ± 31.16 mg/dl.

Management of type 2 diabetic patients was complex: 41% of patients on antiplatelet therapy; 27% on anti-hypertensive; 22% on insulin (includes Oral Hypoglycemic Agent + Insulin); 20.3% on angiotensin converting enzyme inhibitors and 15.6% on statin medications.

CONCLUSIONS —

Family physicians were not adequately following the ADA recommended guidelines for comprehensive management of diabetes patients. Inadequate documentation of medical records may reflect poor diabetes care and comorbid conditions of hypertension and hyperlipidemia were not optimally managed according to ADA guidelines. In short, a wide gap exists between practice recommendations and delivery of diabetes care by peripheral diabetes clinics.

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LIST OF ABBREVIATIONS

ADA	American Diabetes Association
ADs	Associate Diabetologists
ACEI	Angiotensin Converting Enzyme Inhibitors
BIDE	Baqai Institute of Diabetology and Endocrinology
BMI	Basal Metabolic Rate
BMU	Baqai Medical University
BP	Blood Pressure
CHD	Coronary Heart Disease
CVD	Cardiovascular Disease
CV	Cardio-Vascular
DM	Diabetes Mellitus
EMME	Eastern Mediterranean and Middle East Region
ESRD	End Stage Renal Disease
FBG	Fasting Blood Glucose
FPs	Family Physicians
HbA1c	Glycosylated Hemoglobin A1c
HDL	High Density Lipoprotein
IDF	International Diabetes Federation
IGT	Impaired Glucose Tolerance
LDL	Low Density Lipoprotein
PCPs	Primary Care Physicians
PDCs	Peripheral Diabetes Clinics
PVD	Peripheral Vascular Disease

PAD	Peripheral Arterial Disease
RBG	Random Blood Glucose
SEA	South - East Asia
TCs	Total Cholesterols
TGs	Triglycerides
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
WDF	World Diabetes Foundation
WHO	World Health Organization

CHAPTER ONE

INTRODUCTION

1.1 PAKISTAN - A BRIEF COUNTRY PROFILE

Pakistan is the sixth most populous country in the world and has one of the largest Muslim populations in the world (1). It is a poor developing country situated in South Asia.

A brief overview of the country is given below:

A Brief Country Profile:

Full name: Islamic Republic of Pakistan

Term for Citizen(s): Pakistani

Independence: August 14, 1947, from Britain

Flag: Pakistan's flag is green with a narrow vertical white band on its left side. A white crescent and star are in the center of the green band. Green signifies the Muslim majority, white denotes minorities, the crescent represents progress, and the star symbolizes light and knowledge. (2)

Population: 164.7 million

Capital: Islamabad

Largest city: Karachi

Area: 796,095 sq km (307,374 sq miles), excluding Pakistani-administered Kashmir (83,716 sq km/32,323 sq miles)

Male life expectancy at birth (years) 62.7

Female life expectancy at birth (years) 64.8

Infant mortality rate (per 1000 live births) 68.8

Under five mortality rate (per 1000 live births) 98.0 (2005)

Maternal mortality ratio (per 10000 live births) 350.0 (2005)

% Population growth rate 1.8 in 2007

% Population below 15 years 36.9 in 2007

% Population 65 years and over 4.3 in 2007

Total Fertility Rate: 3.71 children born/woman in 2007

Population below poverty line: 24% (Fiscal Year 05/06)

Literacy rate: age 15 and over can read and write

Male: 63% / Female: 36% / Total: 49.9% in 2005

People: Punjabi (66%), Sindhi (13%), Pakhtun, (10.9%), Muhajir - immigrants from India at the time of partition and their descendants (7.6%), Balochi (2.5%)

Official languages: English and Urdu

Languages spoken: Punjabi, Sindhi, Pashto, Urdu, Balochi, English and many other local languages

Religions: Islam (97%), Hinduism, Christianity and others (3%)

Monetary unit: 1 Pakistani Rupee (PKR) = 100 paisa

Main exports: Textile products, rice, cotton, leather goods, carpets, sports goods, handi-crafts, fish and fruit

GNI per capita: US \$690 (World Bank, 2006)

Major Political Parties: Pakistan Muslim League - Quaid-i-Azam (PML-Q); Pakistan People's Party (PPP); Muttahida Majlis-i-Amal (MMA) (a coalition which includes the Jamaat-e-Islami and the Jamiat-Ulema-Islami) ; Pakistan Muslim League - Nawaz (PML-N); Muttahida Qaumi Movement (MQM); and Awami National Party (ANP)

Head of State: President Pervez Musharraf

Interim Prime Minister: Mohammadmian Soomro (3, 4, 5, 6)



1.1.1 Geography

Pakistan shares borders with four countries: India to the east, China to the north east, Iran to the south west and Afghanistan along the western and northern boundaries. Pakistan's coastline on the Arabian Sea is 1,064 km long. Total area of Pakistan is 803,940 sq km of which land is 778,720 sq km & water is 25,220 sq km.

The climate can be roughly split into 3 seasons: cool (October through February), hot (March through June), and wet (July through September). There are, however, significant regional variations.

Pakistan is divided into four provinces: Balochistan, the North West Frontier Province (NWFP), Punjab and Sindh. In addition to the 4 provinces there are also the Federally Administered Tribal Areas (FATA), the Federally Administered Northern Areas (FANA), and the Islamabad Capital Territory. Pakistan-administered Kashmir is known in Pakistan as Azad Jammu and Kashmir (AJK). (2)

1.1.2 History:

Pakistan was part of British India prior to partition in 1947 and has a long history of settlement and civilization including the Indus Valley Civilization. The region has been invaded by the Greeks, Persians, Arabs, Afghans, Turks and Mongols. The territory was incorporated into British India in the nineteenth century. Since its independence on 14 Aug 1947, the country has been characterized by periods of military and economic growth interspersed with political instability (1).

1.1.3 People:

Pakistan has a large, mostly rural population with a high rate of growth. Population is estimated to be 164,741,000 as of 2007. According to Pakistan's 1998 census the population is clustered in the eastern provinces of Punjab and Sindh, which contain 78.6 percent of the total population mainly in the rural area. Only Sindh had roughly equal rural and urban populations (51.2 percent and 48.8 percent, respectively).

The five main ethnic groups are Punjabi (66%), Sindhi (13%), Pashtun, (10.9%), Muhajir - immigrants from India at the time of partition and their descendants (7.6%), and Balochi (2.5%)

Languages mainly spoken are Punjabi, Sindhi, Pashtun, Urdu, Balochi, English and many other local languages. (2)

1.1.4 Population Demography:

Pakistan's fast-growing population has a substantial proportion of youths. According to 2007 estimates, 37% of the country's population is less than 14 years of age. Around 58.8% of the population is between 15-64 years while 4.3% of the population is 65 years or above. The overall median age is around 20.9 years while it is 20.7 years for males and 21 years for females.

Sex ratio is 1.045 male(s)/female for the total population.

Life expectancy at birth for the total population is 63.75 years. It is 62.73 years for males and 64.83 years for females.

Infant mortality rate (per 1000 live births)	68.8
Under five mortality rate (per 1000 live births)	98.0 (2005) (6)
Maternal mortality ratio (per 10000 live births)	350.0 (2005) (6)
% Population growth rate	1.8 (2007)
% Population below 15 years	36.9 in 2007
% Population 65 years and over	4.3 in 2007
Population growth rate:	1.828%
Total Fertility Rate:	3.71 children born/woman (2007)
Birth rate:	27.52 births/1,000 population
Death rate:	8 deaths/1,000 population (5, 3)

1.1.5 Education:

50% of the adult population is illiterate. Pakistan has low indicators of educational attainment, and education has been under funded for decades. Free primary education is a constitutional right and is compulsory in every province except Balochistan (5). Education in Pakistan is divided into five levels: primary (grades one through five); middle (grades six through eight); high (grades nine and ten, leading to the Secondary School Certificate); intermediate (grades eleven and twelve, leading to a Higher Secondary school certificate); and university programs leading to graduate and advance degrees. Pakistan also has a parallel secondary school education system in private schools, which is based upon the curriculum set by the University of Cambridge. Some students choose to take O level and A level exams, which are administered by the British Council, in place of government exams. All academic education institutions are the responsibility of the provincial governments. The federal government mostly assists in curriculum development, accreditation and some financing of research (1). In addition to public and private schools, an indeterminate number of mosque-administered madrassas provide free room, board, and theological education, which makes them an attractive option for poor families. (2)

1.1.6 Economy

Pakistan's economy depends mostly on agriculture. The GDP - per capita (PPP) of the country is \$2,600 according to 2006 estimates. Unemployment rate is 6.5% plus substantial underemployment while 24% of the population lives below poverty line. Poverty line is the minimum level of income deemed necessary to achieve an adequate standard of living. Definition of poverty varies considerably amongst nations and the definition of poverty line is significantly higher in developed nations than in developing nations. Here it is taken as one US dollar. (3)

An earthquake measuring 7.6 struck northern Pakistan on 8 October 2005. The tremors were felt as far away as India and Afghanistan. The earthquake affected 3.5 million people and cost the lives of over 75,000 people in the region. Almost 2.5 million people have lost their homes. This natural disaster also badly affected the financial resources of the country. Pakistan with great help from the international community has moved from emergency relief to long-term reconstruction and rehabilitation of the affected area. (5)

1.1.7 Politics

Parliament consists of two Houses i.e., the Senate (Upper House) and the National Assembly (Lower House). The Senate is a permanent legislative body and symbolises a process of continuity in the national affairs. It consists of 100 members. The four Provincial Assemblies, Federally Administered Tribal Areas and Federal Capital form its electoral college. The National Assembly has a total membership of 342 elected through adult suffrage (272 general seats, 60 women seats and 10 non-Muslim seats) (7).

Each province has a governor appointed by the president, and provinces also have an elected legislative assembly and a chief minister who is the leader of the legislative assembly's majority party or coalition. The chief minister is assisted by a council of ministers chosen by the chief minister and formally approved by the governor. Federally administered areas also

have their own legislative entities, which have had less autonomy from the federal government than provincial legislatures. (2)

Following the assassination of popular opposition leader Benazir Bhutto, general elections were held in Pakistan on 18 Feb, 2008 to elect members of the national assembly of Pakistan. Pakistan's two main opposition parties, the Pakistan Peoples Party (PPP) and the Pakistan Muslim League - Nawaz (PML (N)) won majority of seats in the election, although the Pakistan Muslim League –Quaid e Azam (PML (Q)) was actually second in popular vote. The PPP and PML (N) are to form the new government (1).

1.1.8 Lifestyle and Physical Activity

According to rural and urban settings the lifestyle of the Pakistani people is different. The rural culture favors a labor-intensive lifestyle. In the rural areas apart from household work the women also help their men in the fields and in looking after the livestock. Lifestyle changes that occur due to urbanization are leading more people to have sedentary occupations with insufficient physical activity. This is one of the reasons why we are seeing the burden of obesity in the form of Diabetes on most world population. The urban Pakistani culture also does not favour doing extra physical exercise apart from the requirements of the daily chores.

The traditional Pakistani diet is spicy with excessive oil and is another contributing factor to obesity and later in life to diabetes. The staple Pakistani food is wheat and "Roti" – a kind of bread made from flour is usually taken with all meals. The type of food consumed by the population generally depends on their socioeconomic status, occupation and level of physical activity. The people in the city have high caloric intake and prefer to eat meat mostly beef, mutton and chicken. The nutrient importance of fruits and vegetables is generally not taken into consideration while presenting a meal. Large amount of carbohydrates and fats are consumed as compared to small intake of fiber.

1.1.9 Health Care System

Pakistan's health indicators, health funding, and health and sanitation infrastructure are generally poor, particularly in rural areas. About 19 percent of the population is malnourished—a higher rate than the 17 percent average for developing countries—and 30 percent of children under age five are malnourished. Leading causes of sickness and death include gastroenteritis, respiratory infections, congenital abnormalities, tuberculosis, malaria, and typhoid fever.

According to 2002 government statistics, there were 12,501 health institutions nationwide, including 4,590 dispensaries, 906 hospitals with a total of 80,665 hospital beds, and 550 rural health centers with a total of 8,840 beds. (2)

In 2003

Health Expenditure indicators:

GDP per capita 550

Total expenditure on health of % of GDP 2.4

General government expenditure on health as % of total health expenditure 27.7

In 2005

Human and physical resources indicators:

Physicians per 10000 population 8.0

Dentists per 10000 population 1.00

Nursing and midwifery personnel per 10000 population 3.0

Coverage with primary health care services indicators:

Population with access to local health services, total (%) 96

Population with access to local health services, urban (%) 100

Population with access to local health services, rural (%) 92

Contraceptive prevalence rate (%) 34

Antenatal care coverage (%) 41 (6)

1.2 BACKGROUND:

Diabetes Mellitus (DM) is a leading cause of death and disability. Improvement of the quality of diabetes care is essential for reducing the incidence of diabetes complications. DM is a life long disease which places grave economic burden not only on the person having diabetes but also affects the patient's family financially. In the past type 2 diabetes mellitus (T2DM) was assumed to be a disease of the rich man and usually striking someone after 40 years of age. But now with the great change in lifestyles (unhealthy diet and lack of physical activity) and urbanization, T2DM is emerging in a much younger age group and in some parts of the world even among children as young as 8 years of age. T2DM is being reported in children from the United States, Canada, Japan, Hong Kong, Australia, New Zealand, Libya, and Bangladesh. (8)

1.2.1 Diabetes Mellitus

Diabetes mellitus is a chronic condition that arises when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin produced or both. This causes hyperglycemia (an abnormally high concentration of glucose in the blood), which seriously damages many of the body's systems, especially the blood vessels and nerves. There are two basic forms of diabetes: type 1 and type 2. People with type 1 diabetes do not produce insulin as a result of autoimmune destruction of beta cells. People with type 2 diabetes produce insulin but cannot use it effectively. (9) Symptoms of marked hyperglycemia include polyuria, polydipsia, weight loss, sometimes with polyphagia, and blurred vision. Impairment of growth and susceptibility to certain infections may also accompany chronic hyperglycemia. (10)

1.2.2 Global Burden of Diabetes Mellitus

Diabetes is one of the most costly diseases ever in both human and economic terms. Chronic diseases are the largest cause of death in the world led by cardiovascular disease (17 million deaths in 2002, mainly

from ischemic heart disease and stroke) and followed by cancer (7 million deaths), chronic lung diseases (4 million), and diabetes mellitus (almost 1 million). (11) In 2003, the International Diabetes Federation (IDF) estimated that almost 200 million people around the world had diabetes. By 2025 this figure is expected to rise to 333 million, amounting to 6.3% of the world's population living with diabetes. (12) In developing countries, the number of people with diabetes will increase by 150% in the next 25 years. (13) In developed countries most people with diabetes are above the age of retirement, whereas in developing countries those most frequently affected are between 35 and 64 years of age. (13) Almost 50% of people with T2DM are not aware that they have the condition. India and Pakistan are in the world's top 10 in terms of the highest number of people with diabetes in 2003 (respectively 35.5 million and 6.2 million), highest projected number of people with diabetes in 2025 (respectively 73.5 and 11.6 million), and highest current and projected number of people with impaired glucose tolerance. (14) Article 25 of the Declaration of Human Rights states that: 'everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including medical care.' This basic human right is a luxury that many especially in the developing world cannot afford. (15)

In Pakistan alone:-

- ◆ The IDF gives an estimate of 12% prevalence in Pakistan, with a total of 8.8 million people with diabetes in 2000. (16)
- ◆ It is estimated that 6.2 million people have diabetes, representing 8.5 % of the adult population. (12)
- ◆ According to WHO, the number of people with diabetes in Pakistan during 1995-2025 is expected to be about 14.5 million (17). While over the next 10 years according to WHO death from diabetes in Pakistan is expected to increase by 51%. (18)
- ◆ The high economic burden of diabetes in the Eastern Mediterranean and Middle East (EMME) Region is due to the high prevalence rate coupled with

the high cost of diabetes care and limited resources. A less affluent country such as Pakistan is estimated to spend between 430 and 800 million dollars on diabetes care. (12)

Total monthly expenditures of an average Pakistani household is Rs. 8965 (149 USD), food, clothing and housing, consuming nearly 80% of it. Rs. 260 (4.3 USD) per month (2.9% of the total monthly expenditure) is spent on health reflecting low priority of healthcare. Prevention of diabetes and its complications therefore, is the main stay of diabetes care. (19)

1.2.3 Diabetes Care in Pakistan

It is estimated that in Pakistan 6.2 million people have diabetes, representing 8.5 per cent of the adult population in Pakistan. According to the World Health Organization (WHO), the figure is expected to reach 11.6 million by 2025. (20)

Institutions specializing in diabetes care are limited in number and are concentrated in the big cities. There are no support personnel and very few dietitians. The government faces a major challenge to provide healthcare for everyone especially when 69% of the population lives in rural area. Health facilities are concentrated in the urban areas and the major services are provided by the private sector. (21)

In Pakistan, less than one percent of public expenditure is spent on health and only 20% of health services are provided by the public sector. The result is an ever-increasing gap between availability of services and the population's needs. The private sector plays a major health-care role in Pakistan. The private sector supplies >80% of outpatient healthcare and therefore is a critical resource in efforts to provide accessible, affordable and equitable services. Pakistan's private sector remains largely absent from the health policy table, although there are hopeful signs that this may be changing. The 1995 National Action Plan for health placed special emphasis on diabetes and was designed to ensure the provision of this care. However, the Plan was not fully implemented.

Until several years ago, there was no healthcare facility in Pakistan which offered comprehensive care to the diabetics under one roof. Private sector has now taken the lead as Baqai Medical University in Karachi in 1997 established Baqai Institute of Diabetology and Endocrinology (BIDE). It was first such center in Pakistan offering most comprehensive diabetic care by multidisciplinary team comprising of apart from the diabetologists of dietitians and diabetes educators. In 1999, BIDE started one year diploma in diabetology with the aim to train family physicians in primary diabetes care. All over Pakistan BIDE was the first to set up a special foot clinic for diabetes. In 2006 to improve diabetes care especially foot care in low resource and underserved communities in Pakistan, BIDE became a member of international working group on diabetic foot (IWGDF). This year in 2008 a diploma course for diabetes educators was commenced to create further diabetes awareness among healthcare providers and general public.

In the public sector, Jinnah Postgraduate Medical Center (JPMC) in Karachi, Mayo Hospital and Services Hospital in Lahore have diabetes centers and many other Non Governmental Organizations (NGOs) are also running diabetes clinics. The Dow University of Health Sciences (DUHS) in Jan 2008 established the National Institute of Diabetes and Endocrinology (NIDE) at the Ojha campus of the varsity. This institute in the public sector has now entered its second phase of outdoor patients where consultation is free. It has facility for laser therapy to prevent blindness in diabetics which is available at discounted rates.

1.2.4 Complications of Diabetes

Aggressive management of hyperglycemia, hypertension, dyslipidemia and other risk factors can prevent many complications of diabetes. Diabetes complications are common and almost triple the annual cost of managing diabetes. The long term complications of diabetes are:

Arteriosclerosis, diabetic retinopathy, diabetic nephropathy, diabetic neuropathy, heart disease, stroke, peripheral vascular disease and diabetic foot ulcer.

These complications have been further grouped as microvascular and macrovascular complications.

1.2.4.1 Microvascular complications:

Control of hyperglycemia (target fasting blood glucose level <110 mg/dl, target HbA1c level $\leq 7\%$) and hypertension (target blood pressure $\leq 130/80$ mm Hg) prevents microvascular complications in diabetes.

Microvascular complications include:

i) Diabetic Retinopathy:

Diabetic retinopathy is often asymptomatic in its most treatable stages. Unfortunately, only about half of persons with diabetes receive adequate eye care. Early detection of diabetic retinopathy is critical. Diabetes accounts for 12,000 - 24,000 of new cases of blindness annually and is the leading cause of new cases of blindness in adults age 20 - 74. The most common eye disorder in diabetes is retinopathy. People with diabetes are also at higher risk for developing cataracts and certain types of glaucoma. Retinopathy is a condition in which the retina in the eye becomes damaged. The two primary abnormalities that occur are a weakening of the blood vessels in the retina and the obstruction in the capillaries -- probably from very tiny blood clots. Tight control of blood pressure can also help protect against retinopathy. Aspirin therapy does not help prevent retinopathy. (22)

ii) Diabetic Nephropathy:

The earliest sign of diabetic renal disease is the presence of subclinical increases in urinary albumin excretion, termed microalbuminuria (urinary albumin excretion rate, 30–300 mg/24 hrs). The tiny filters in the kidney (called glomeruli) become damaged and leak protein into the urine. Over time this can lead to kidney failure. Urine tests showing microalbuminuria (small amounts of protein in the urine) are important markers for kidney

damage. Diabetic nephropathy occurs in about 20 - 40% of patients with diabetes and represents a distinct clinical syndrome characterized by albuminuria, hypertension, and progressive renal insufficiency. Diabetic nephropathy can lead to end-stage renal disease (ESRD), a serious condition in which a patient's survival depends on either dialysis or kidney transplantation. (22)

iii) Diabetic Neuropathy:

Persons with diabetes who develop neuropathy may have no symptoms or may experience pain, sensory loss, weakness, and autonomic dysfunction. The two main types of neuropathy are:

- a) Peripheral (affects nerves in the toes, feet, legs, hand, and arms) and
- b) Autonomic (affects nerves that help regulate digestive, bowel, bladder, heart, and sexual function).

Peripheral neuropathy particularly affects sensation. The most serious consequences of neuropathy occur in the legs and feet and pose a risk for ulcers and, in very severe cases, amputation. Peripheral neuropathy usually starts in the fingers and toes and moves up to the arms and legs (called a stocking-glove distribution). Symptoms include:

- Tingling
- Weakness
- Burning sensations
- Loss of the sense of warm or cold
- Numbness (if the nerves are severely damaged, the patient may be unaware that a blister or minor wound has become infected)
- Deep pain

In some cases, neuropathy may mask angina, the chest pain warning for heart disease and heart attack. Patients with diabetes should be aware of other warning signs of a heart attack, including sudden fatigue, sweating, shortness of breath, nausea, and vomiting. If diabetes affects the nerves in the autonomic nervous system, then abnormalities of blood pressure control and bowel and bladder function may occur. In men, erectile dysfunction (impotence) is also associated with neuropathy. (22)

iv) Diabetic Foot Ulcer:

Foot ulcers and amputations are a major cause of morbidity for people with diabetes. Risk factors for these complications are the presence of peripheral neuropathy, altered biomechanics in the foot and peripheral vascular disease. About half of all lower-limb amputations in people with diabetes are preventable. An estimated 15% of patients with diabetes experience serious foot problems. They are the leading cause of hospitalizations for these patients. According to a 2005 study in the *Lancet*, every 30 seconds someone in the world receives a lower limb amputation due to diabetes. About 85% of amputations start with foot ulcers, which develop in about 12% of people with diabetes. Foot infections often develop from injuries. Even minor infections can develop into severe complications. Numbness from nerve damage, which is common in diabetes, compounds the danger since the patient may not be aware of injuries. About one-third of foot ulcers occur on the big toe. A 2003 government survey found that those at higher risk for foot ulcers tend to be people with diabetes who are overweight, smokers, and those with a long history of diabetes. People who have the disease for more than 20 years and are insulin-dependent are at the highest risk. Related conditions that put people at risk include peripheral neuropathy, peripheral artery disease, foot deformities, and a history of ulcers. (22)

1.2.4.2 Macrovascular complications: Preventing these complications in T2DM which is often associated with other cardiovascular risk factors, is a major challenge. They include:

i) Coronary Heart Disease (CHD) and Stroke: Heart attacks account for 60% and strokes for 25% of deaths in patients with diabetes. Diabetes speed the progression of arteriosclerosis (hardening of the arteries). Diabetes can adversely affect blood lipid levels by lowering high density lipoprotein -HDL ("good cholesterol") and increasing triglycerides. This can lead to coronary artery disease, heart attack, or stroke. According to a 2007 study, the risk of stroke doubles within 5 years of type 2 diabetes

diagnosis. Impaired nerve function (neuropathy) associated with diabetes also causes heart abnormalities. Some experts estimate that the mortality rates from neuropathy-related heart conditions range between 15 - 53%. Women with diabetes are at particularly high risk for heart problems. A 2007 study indicated that while progress has been made in reducing mortality rates among men with diabetes, women with diabetes continue to face a high risk of death from heart disease and overall causes. Tight blood sugar control may help protect blood vessels and reduce the risk for blood clotting. Taking a daily aspirin (75 - 162 mg/day) reduces the risk for blood clotting and may help protect against heart attacks and heart disease. In a 2000 study, low-dose aspirin was associated with a 30% lower risk for death from heart disease in adults with type 2 diabetes. Patients should strive for blood pressure levels of less than 130/80 mm Hg (systolic/diastolic). (Controlling systolic pressure may be especially important for reducing the risk for kidney complications.)

ii) Peripheral Vascular Disease (PVD):

People with peripheral vascular disease (PVD) may or may not have symptoms. Because of silent symptoms, many cases of PVD go undiagnosed. This condition is also called as peripheral arterial disease (PAD) and occurs when atherosclerosis affects arteries in the feet and legs or much less commonly the hands and arms. In such cases the arteries become blocked, obstructing oxygen-rich blood flow. PAD is now recognized as a major risk factor for heart disease and stroke. Claudication is crampy leg pain that occurs during exercise, especially walking. The pain is due to insufficient blood flow in the legs (caused by blocked arteries). Intermittent means the pain comes and goes. Intermittent claudication is the most prominent symptom of PAD. The most frequently affected artery in intermittent claudication is the popliteal artery. People with T2DM have three to four times the usual risk for PAD and intermittent claudication. They also tend to develop PAD at earlier ages and suffer more severe cases. In one study it was found that people

with diabetes and intermittent claudication had 30% chance of developing skin ulcers in their legs. (22)

Other diabetes related complications include:

Mental Function and Dementia

Studies indicate that patients with type 2 diabetes face a higher than average risk of developing dementia caused either by Alzheimer's disease or problems in blood vessels in the brain. Problems in attention and memory can occur even in people under age 55 who have had diabetes for a number of years.

Depression

Diabetes doubles the risk for depression. Furthermore, according to one study, depression, in turn, increases the risk for hyperglycemia and complications of diabetes.

Infections

People with diabetes face a higher risk for influenza and its complications, including pneumonia, possibly because the disorder neutralizes the effects of protective proteins on the surface of the lungs. In fact, deaths among people with diabetes increase by 5 - 15% during flu epidemics. Everyone with diabetes should have annual influenza vaccinations and a vaccination against pneumococcal pneumonia. Women with diabetes face a significantly higher risk for urinary tract infections, which are likely to be more complicated and difficult to treat than in the general population.

Diabetes increases the risk for other conditions, including:

- Hearing loss
- Periodontal disease
- Carpal tunnel syndrome

- Nonalcoholic fatty liver disease, also called nonalcoholic steatohepatitis (NASH), a particular danger for people who are obese.
- Colorectal cancer
- Uterine cancer (22)

1.2.5 American Diabetes Association (ADA):-

The American Diabetes Association was founded in 1940 as a scientific and medical organization serving people with diabetes. The mission of the ADA is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. To fulfill this mission, the ADA funds research, publishes scientific findings, provides information and other services to people with diabetes, their families, health professionals and the public. The Association is also actively involved in advocating for scientific research and for the rights of people with diabetes. The ADA writes standards of medical care for people with diabetes. These guidelines give doctors the most up-to-date information on caring for their patients with diabetes. (23)

ADA Recommendations for Adults with T2DM:-

Diabetes is a chronic illness that requires continuing medical care and patient self-management education to prevent acute complications and to reduce the risk of long-term complications. Every year, ADA issues Clinical Practice Recommendations, a series of updated recommendations, to help health care providers treat people with diabetes using the most current research available.

The ADA 2004 recommendations for Adults with T2DM have been applied for this study.

Glycemic Control:

Biochemical Index	Normal	Goal	Additional Action Suggested
Pre-prandial glu (mg/dl)	< 110	80-120	<80; >140
Bedtime glu (mg/dl)	< 120	100-140	<100; >160

Hemoglobin A1c (%) < 6 < 7 > 8

Order of priorities for treatment of diabetic dyslipidemia in adults:

Low-Density Lipoprotein (LDL) < 100 mg/dl

< 70 mg/dl *very high risk patients

Triglycerides (TGs) ≤ 150 mg/dl

Total cholesterol (TCs) ≤ 200 mg/dl

High-Density Lipoprotein (HDL) > 40 mg/dl in men

> 50 mg/dl in women

Hypertension goals in DM

Blood pressure (BP) ≤ 130/80 mmHg

Assessment of Glycemic Control

Recommendations:

- Perform glycosylated hemoglobin A1c (HbA1c) at least two times/year in patients who are meeting treatment goals
- Perform HbA1c quarterly in patients not meeting glycemic goals

Management of Diabetes Complications

Cardiovascular Disease (CVD)

♦Patients > 55 years, ± Hypertension (HTN) with another Cardiovascular (CV) risk factor:

Angiotensin-Converting Enzyme Inhibitors (ACEI) should be considered to reduce risk of CV events

♦ All patients with diabetes and HTN should be treated with ACEI or Angiotensin II Type 1 Receptor Blockers (ARB)

♦ If needed to achieve blood pressure targets: Add a thiazide diuretic.

Lipid Management

Screening

For lipid disorders:

♦ Lipid profile at least annually and more often if needed

If LDL < 100, HDL > 50, and TG's < 150:

Primary goal:

Lower LDL < 100 mg/dl

Patients > 40 years of age with TC \geq 135 mg/dl, without overt CVD:

LDL reduction of 30 – 40 % regardless of baseline is recommended

Very high risk patients:

- ◆ Acute Coronary Syndrome or previous CV events
- ◆ More aggressive therapy to achieve LDL < 70 mg/dl may lead to a significant reduction in further events.

Albumin Excretion:

Category	Spot collection (microgms/mg creatinine)
Normal	< 30
Microalbuminuria	30-300
Clinical albuminuria	> 300

If microalbuminuria or albuminuria is present then place patient on ACE inhibitor.

Anti-platelet therapy

Primary prevention:

Acetylsalicylic acid (ASA) therapy (75-162 mg/d) in diabetes patients with increased CV risk:

- ◆ Age > 40
- ◆ Family history of CVD
- ◆ HTN
- ◆ Smoking
- ◆ Dyslipidemia
- ◆ Albuminuria

Secondary prevention:

ASA therapy (75-162 mg/day) in diabetes patients with:

- ◆ History of Myocardial Infarction (MI)
- ◆ Vascular bypass procedure
- ◆ Stroke or Transient Ischemic Attack (TIA)

- ♦ PVD
- ♦ Intermittent Claudication
- ♦ Angina

Should not be recommended:

Age < 21

Note: Individuals under the age of 30 have not been studied.

Nephropathy screening

T2DM:

Perform test annually for presence of Microalbuminuria

Nephropathy treatment

T2DM, HTN, microalbuminuria, and renal insufficiency:

ACEI and ARBs delay the progression to macroalbuminuria

T2DM, HTN, macroalbuminuria, and renal insufficiency:

ARBs delay the progression of nephropathy

Retinopathy screening

Recommendations: T2DM:

Initial dilated and comprehensive eye exam shortly after diagnosis of diabetes

Subsequent examinations should be repeated annually. (24)

Use of anti-platelet agents, statins and ACE inhibitors to treat T2DM with and without symptomatic atherosclerosis showed a reduction in CV risk and mortality. (25)

However, few studies have focused on specialist practice but it is unclear whether specialists were able to meet ADA guidelines. (26, 27) In order to achieve an optimal care for diabetic patients, BIDE has initiated a program to train physicians as Associate Diabetologists (ADs) to support the Peripheral Diabetes Clinics (PDCs) with a view to improve quality of care. It is thought that such early intervention can translate into better metabolic control and, ultimately, the prevention of diabetes

complications. But it is not known whether the new training program has impacted on the quality of care rendered to the diabetic patients.

Family Physicians (FPs) as the primary care providers play a key role in the diagnosis and treatment of health problems in the community. The study analyzed the impact of primary diabetes care given at PDCs by trained ADs from BIDE at their clinical practice. Furthermore, the purpose of this study was to examine the level of diabetes care provided to the population coming to PDCs in Karachi, Pakistan.

1.3 RATIONALE OF THE STUDY

Several studies involving physician surveys, chart audits and reviews of administrative databases have shown that the quality of diabetes care by primary care physicians (PCPs) is suboptimal. (28, 29, 30, 31) T2DM is frequently not diagnosed until complications appear, and approximately one-third of all people with diabetes may be undiagnosed. (24) Long-term complications of diabetes include retinopathy with potential loss of vision; nephropathy leading to renal failure; peripheral neuropathy with risk of foot ulcers, amputation, and Charcot joints; and autonomic neuropathy causing gastrointestinal, genitourinary, and cardiovascular symptoms and sexual dysfunction. (32) Therefore, early identification and treatment of these diabetes complications may reduce the severity of the complications.

As part of a program to reduce these long-term complications at primary preventive care level, the study will determine how frequently assessment of cardiovascular risk factors, fundoscopic examinations, (referral to an ophthalmologist) and foot examinations are provided to T2DM patients. (33) Studies have shown that complications of diabetes can be slowed or prevented by better management on the part of the health care team and patient. (34) A single study used computerized data records from three managed care organizations to assess the prevalence of HbA_{1c} tests, dilated eye examinations, and urine protein assessments (both microalbuminuria and macroalbuminuria) in patients with diabetes. (35)

Despite its high prevalence, serious long term complications, and established evidence-based guidelines for management (24, 36), translation of practice recommendations to care is still deficient in Asian (37) and developed countries (38, 39, 40).

The primary care sector is of key importance for the management of patients with diabetes mellitus. With this in view, BIDE started training FPs nine years ago with an aim to deliver primary diabetes care to the common man, and to establish a network of PDCs across the country.

A study similar to our study has not been done in the South Asia region. It was hoped that the outcome of this study will show us what measures are further needed to improve the quality of care given to T2DM patients. As we know that early diabetic management can delay worsening of already established complications, therefore, we can evaluate the specialized diabetic management training being offered at these PDCs. If necessary in the long run even recommend local diabetic guidelines most appropriate for the local ethnic population.

1.4 LITERATURE REVIEW

Diabetes mellitus is now recognized as one of the major health problem facing the country. The prevalence of diabetes mellitus in Pakistan is high, 12% of people above 25 years of age suffer from the condition (41). Majority of those suffering from diabetes mellitus have T2DM and its related complications. T2DM is an important cause of morbidity and mortality. Looking after and managing this increased pool of diabetics will seriously affect the health services. This issue must be given a serious thought by our health planners and all others concerned with health delivery system in Pakistan. Prevalence of T2DM is increasing dramatically because of population aging and sedentary lifestyle particularly in South Asia. (42, 43)

A study was conducted in USA, using ADA guidelines to evaluate control of CVD risk factors by auditing the medical records of patients suffering from diabetes and hypertension. 90.9% had type 2 diabetes, and 26.7% met

the target BP 130/85 mmHg. A total of 35.5% met the goal LDL cholesterol level of <100 mg/dl, 26.7% had an HbA1c <7%, and 45.6% were on antiplatelet therapy. Only 3.2% of patients met the combined ADA goal for BP, LDL cholesterol, and HbA1c. (42)

A cross sectional survey was conducted in India to evaluate the quality of care in known diabetic patients from the middle- and high-income group populace of Delhi. Thirty areas were selected for a house-to-house survey to recruit a minimum of 25 subjects (known diabetes ≥ 1 year; aged 35–65 years) per area. Data were collected by interview, by blood sampling, and from medical records. A total of 819 subjects were enrolled and in total, 13.0% (95% CI 9.6–17.3) of the patients had HbA1c estimation and 16.2% (13.5–19.4) had a dilated eye examination in the last year, 32.1% (27.5–36.6) had serum cholesterol estimation in the last year, and 17.5% (14.2–21.5) were taking aspirin. An estimated 42.0% (37.7–46.2) had an HbA1c value >8%, 40.6% (36.5–44.7) had an LDL cholesterol level >130 mg/dl, and 63.2% (59.6–66.6) had blood pressure levels >140/90 mmHg. The conclusion was that a wide gap exists between practice recommendations and delivery of diabetes care in Delhi. (43)

A retrospective study was conducted in USA, to determine whether rural health care providers are compliant with ADA clinical practice guidelines for glycemic, blood pressure, lipid management, and preventative services. The medical records of 399 patients 45 years of age and older were reviewed, with a definitive diagnosis of diabetes seen for primary diabetes care at four rural health facilities in Montana between 1 January 1999 and 1 August 2000. Glycemic testing was adequate (85%), and glycemic control (HbA1c $7.43 \pm 1.7\%$) was above the national average. Comorbid conditions of hypertension and dyslipidemia were not as well managed. Mean systolic blood pressure (SBP) was 139 ± 18.8 mmHg and LDL was 119 ± 33 mg/dl. Of 399 patients, 11 were considered as needing no additional treatment based on ADA guidelines of an HbA1c level <7%, a BP <130/85 mmHg, and a LDL level <100 mg/dl. Monofilament testing

and dilated eye examinations were poorly documented, as were immunizations. (44)

A study in USA was conducted to estimate the proportion of U.S. adults with diabetes who meet ADA clinical practice recommendations. Data from the 1999–2002 National Health and Nutrition Examination Survey was used to estimate the proportion of adults with diabetes meeting ADA recommendations for HbA1c, HDL cholesterol, LDL cholesterol, triglycerides, blood pressure, renal function and smoking. Among U.S. adults with diabetes in 1999–2002, 49.8% had HbA1c <7%; 27.4, 36.0, and 65.0% were classified as low risk for HDL cholesterol, LDL cholesterol, and triglycerides, respectively. Nearly 40% met blood pressure recommendations and 66% had normal renal function. The conclusion of the study was that achievement of ADA clinical practice recommendations is far from adequate in U.S. adults with diabetes. (45)

Another study in USA was conducted to determine whether ADA guidelines can be met in the context of routine endocrinology practice. Charts were reviewed for a group of patients who were examined in 1998, followed for ≥ 1 year, and had two or more visits during that year. Process measures and metabolic outcomes were studied for patients with T2DM. Of a total of 121 patients with type 2 diabetes many had complications: 80% had hypertension, 64% had hyperlipidemia, 78% had neuropathy, 22% had retinopathy, and 21% had albuminuria. Management of type 2 diabetic patients was complex: 31% used oral hypoglycemic agents and insulin, and 26% used insulin alone; 42% of patients taking insulin therapy injected insulin three or more times per day. Within 12 months, 74% of patients had dilated eye examinations, 70% had lipid profiles, and 55% had urine albumin screening. Of the patients, 87% had a foot examination at their last visit. Blood pressure levels averaged 133/72 mmHg, cholesterol levels averaged 4.63 mmol/l, triglyceride levels averaged 1.99 mmol/l, HDL cholesterol levels averaged 1.24 mmol/l, and LDL cholesterol levels averaged 2.61 mmol/l. Random blood glucose levels averaged 8.0 mmol/l, and HbA1c levels averaged $6.9 \pm 0.1\%$. This study provided

evidence that ADA guidelines can be achieved in specialist practice. Although comorbidities and diabetes complications were frequent, patients with T2DM had good glycemic control. Most patients had appropriate screening examinations, and BP and lipid outcomes were also good. (46)

1.5 OBJECTIVES OF THE STUDY

1.5.1 General Objective

The main aim was to determine if ADA recommended guidelines for diagnosis and care of diabetes taught to FPs during their diploma training in diabetology was implemented in their daily practice. If yes then to what extend.

1.5.2 Specific Objectives

(i) To observe any deviation from the ADA recommended guidelines related to risk assessments like: recording weight, smoking, BP control, measuring HbA1c values, lipid managements, conducting foot inspections, fundus examinations and monitoring for early diabetic nephropathy.

(ii) To know the frequency of chronic complications in the T2DM population.

CHAPTER TWO

MATERIALS AND METHODS

2.1 Research Setting:-

The research took place in Karachi, which is Pakistan's largest cosmopolitan city with a population of more than 16 million. Karachi is the country's industrial center and the provincial capital of Sindh. It is located in the south of Pakistan, on the coast of the Arabian Sea and also has the largest port of the country. The metropolitan area along with its suburbs comprises the world's fourth most populated city, spread over 3,530 square kilometers. (47) The city credits its growth to the mixed populations of economic and political migrants and refugees from different national, provincial, linguistic and religious origins that have largely come to settle here permanently.

At present the City-District of Karachi is divided into 18 towns governed by elected municipal administrations. The towns are as:

Baldia Town, Bin Qasim Town, Gadap Town, Gulberg Town, Gulshan Town, Jamshed Town, Keamari Town, Korangi Town, Landhi Town, Liaquatabad Town, Lyari Town, Malir Town, New Karachi Town, North Nazimabad Town, Orangi Town, Saddar Town, Shah Faisal Town and SITE Town.

The towns are sub-divided into 178 localities governed by elected union councils (UC's). Each UC is a body of thirteen directly elected members that includes a Town Nazim (mayor) and a Naib Nazim (deputy mayor). (48)

2.2 Study Area:- The retrospective study was conducted in four PDCs that are functioning as primary preventive centers for DM in their localities.

2.3 Study Population:- general population, living in middle and low socio-economic urban areas of Karachi, mainly in the Gulberg, Gulshan, Liaquatabad, and Orangi townships.

2.4 Research Design

This study was conducted at selected PDCs which are run by one year diploma in Diabetology trained family physicians, known as Associate Diabetologists. These PDCs are affiliated with BIDE, an integral part of Baqai Medical University (BMC), Karachi, Pakistan.

The design was a retrospective study, including 691 medical records of T2DM patients which were reviewed to know the status of their primary care at the various PDCs. The review included non pregnant diabetic patients 20 years of age and older with a definitive diagnosis of T2DM. These patients were seen on their first visit for primary diabetes care at four PDCs in four townships of Karachi district between 1 Jan 2005 to 29 Dec 2006. The entire medical records were examined for evidence of documentation of testing and treatment. Variables from medical records included:

Patient demographics (gender, age), height, weight, Body Mass Index (BMI), family history of DM, history of tobacco consumption, measures of glycemic control (fasting blood glucose, random blood glucose and glycosylated hemoglobin A1c -HbA_{1c}), systolic blood pressure (SBP), diastolic blood pressure (DBP), lipid profile, urine detailed report especially for albumin, microalbuminuria, 24 hrs urinary protein, 24 hrs Creatinine clearance, serum Creatinine and documentation of or referral for dilated eye examination and lower limb assessment (pulses, reflexes, touch and vibrations). Diagnosis of and treatment of chronic comorbid conditions such as hypertension, dyslipidemia, nephropathy and cardiovascular disorder were also recorded.

There was no patient contact or testing performed as part of this study. All information were collected as found in medical records at the four PDCs. Information had been recorded in the patient's medical forms according to the PDCs usual practices.

2.5 Sample Selection

2.5.1 Criteria for Inclusion

All non-pregnant adults aged 20 years and older suffering from T2DM at the time of their registration at the PDCs for treatment. These patients were registered following a routine visit by T2DM outpatients at the PDCs between 1 Jan 2005 to 29 Dec 2006.

2.5.2 Criteria for Exclusion

Those pregnant, aged less than 20 years and suffering from type 1 DM were not included in the study.

2.6 Selection Procedure

The medical records of T2DM patients at the PDCs between 1 Jan 2005 to 29 Dec 2006 that fulfilled the inclusion criteria were included in the study. During this period 691 medical records met the inclusion criteria and were reviewed and selected for inclusion in our study.

2.7 Data Collection:

All related variables found on the medical records were used to assess whether recommended ADA guidelines (2004) for T2DM management are being implemented by the trained FPs or not in this study.

2.7.1 Variable definition

In our study biochemical and clinical information from T2DM patients' medical records were obtained from the following relevant variables:

Demographic variables

- Gender – physical appearance of sex (male or female)
- Age – expressed in years

Age was categorized into three groups as:

20-40 years

41-60 years and

≥61 years old

The duration of diabetes grouped as:

Duration of Diabetes:

1 = < 2 years

2 = 2 – 10 years

3 = >10 years

Clinical variables

▣ Tobacco Consumption

▣ Family history of DM

▣ Weight – expressed in Kilograms and measured by using portable weight machine.

▣ Height – expressed in centimeters and measured with the subject standing barefoot with both heels together erect against a wall having markings in centimeters.

▣ Body Mass Index (BMI)

BMI was calculated according to the formula $BMI = \text{weight}/\text{height}^2$ (kg/m^2). Obesity taken as $BMI > 25 \text{ kg}/\text{m}^2$ as suggested by the Asian cut off levels.

Indian Asians generally have high upper-body adiposity, causing higher insulin resistance, despite having a lean BMI. In February 2000, the WHO Regional Office for the Western Pacific, the International Association for the Study of Obesity, and the International Obesity Task published provisional recommendations for adults in Asia-Pacific as overweight at $BMI > 23 \text{ kg}/\text{m}^2$ and obesity at $BMI > 25 \text{ kg}/\text{m}^2$ (49).

According to the new recommendations the Asian cut off values for BMI used:

BMI: (kg/m^2)

Underweight = 1 ($< 18.5 \text{ kg}/\text{m}^2$)

Normal = 2 ($18.5 - 22.9 \text{ kg}/\text{m}^2$)

Overweight = 3 ($23 - 25 \text{ kg}/\text{m}^2$)

Obese = 4 ($> 25 \text{ kg}/\text{m}^2$)

■ Blood pressure (BP)

Hypertension (HTN) defined as either BP >140/90 mmHg or isolated SBP and DBP of >140 and 90 mmHg respectively and measured by mercury sphygmomanometers.

Diagnosis of Hypertension: In our patients, diagnosis of hypertension was recorded if patient was documented with BP >140/90 mmHg or on antihypertensive treatment.

Blood pressure control taken as:

SBP: (mm Hg)

≤130 mm Hg = Normal

>130 mm Hg = Sys. Hypertension

DBP: (mm Hg)

≤80 mm Hg = Normal

>80 mm Hg = Dias. Hypertension

HTN:

≤130/80 mmHg = Normal

>140/90 mmHg = Hypertensive

■ Fundoscopy

The fundus examined using Vista 20 direct ophthalmoscope by a diabetologist. Retinopathy classified as normal background (presence of microdots and hard exudates), pre-proliferative and proliferative (presence of soft exudates and new vessels) or maculopathy.

■ Foot Examination

Peripheral neuropathy defined as absent touch or vibratory sensations of the feet. Touch sensation assessed by 10gm monofilament and vibration sensation by 128 Hz frequency tuning fork. A standardized filament called monofilament is pressed against part of the foot. When the filament

bends, its tip is exerting a pressure of 10 grams. (50) Subjects with absent dorsalis pedis or posterior tibial pulses on examination with or without a history of intermittent claudication labeled as having peripheral vascular insufficiency (PVI).

- ▣ Aspirin
- ▣ Statin
- ▣ ACE Inhibitors
- ▣ Anti Hypertensive
- ▣ Insulin

Laboratory variables

- ▣ Fasting Blood Glucose (FBG)

FBG estimated by glucose oxidase method.

- ▣ Random Blood Glucose (RBG)

- ▣ HbA1c

Good glycemic control was defined as HbA1c <7%. Glycemic control assessed by measuring HbA1c by DiaSTAT Hemoglobin A1c Analyzer, Bio-Rad. HbA1c further grouped as:

≤7	(Good)
>7 & ≤8	(Fair)
>8 & ≤9	(Poor)
>9	(Bad)

- ▣ Serum Creatinine

- ▣ Proteinuria

Nephropathy defined as protein > 1+ on dipstick (Combur 10, Roche Diagnostics) with no other abnormal findings on urinary examination.

- ▣ Microalbuminuria

- ▣ 24 hrs Proteinuria

- ▣ 24 hrs Creatinine Clearance

- ▣ Lipid Profile – TGs, TC, LDL and HDL

Enzymatic methods (GPO-PAP and CHOD-PAP, Roche Diagnostics) used for lipid profile tests.

Total Cholesterol:

≤ 200 mg/dl

> 200 mg/dl

Total cholesterol-to-HDL ratio (TC/HDL Ratio)

The usual method of calculating the risk of atherosclerosis is calculating the ratio of total cholesterol to HDL cholesterol which can be obtained by dividing total cholesterol by HDL cholesterol.

Reports from the Framingham Heart Study suggest that for men, a total cholesterol-to-HDL ratio of 5 signifies that they're at average risk for heart disease; 3.4, about half the average; and 9.6, about double the average. Women tend to have higher HDL levels, so for them, a ratio of 4.4 signifies average risk; 3.3 is about half the average; and 7, about double. Other risk factors to be considered for assessing heart disease risk and determining steps that should be taken to reduce it include body weight, family history, and HDL and LDL cholesterol levels. (51)

TGs:

≤ 150 mg/dl

> 150 mg/dl

HDL:

Males > 40 mg/dl

Females > 50 mg/dl

LDL:

≤ 100 mg/dl

> 100 mg/dl

2.7 Data handling

The data was entered into Microsoft Excel 2002 and this raw data was checked in Karachi, Pakistan. After arriving in Oslo, Norway, the raw data

in Excel was converted to SPSS 16.0 for Windows software for data analysis.

2.8 Statistical Analysis

The data was analyzed on SPSS version 16.0. Demographic results for age, sex, duration of T2DM, medication used, and presence of other diagnosis were descriptive. Frequencies, cross-tabs (Chi-square test) and measures of central tendency were used to compare medical record information with ADA standards.

In order to assess association of chronic complications with age and duration of diabetes, subjects were categorized into two age groups and two groups for duration of diabetes. Frequency of chronic complications in relatively younger and older subjects and in subjects with shorter and longer duration of diabetes was calculated. We used Chi-square test to assess the statistical significance of these differences. Statistical significance set at $p < 0.05$.

2.9 Ethical issues

The medical records of the selected patients evaluated without any breach of confidentiality regarding their identification code. Approval was sought and given by the Ethical Committee in Norway and the study carried out according to the Helsinki declaration.

CHAPTER THREE

RESULTS

3.1 Findings of the Study

The medical records of 691 T2DM patients including 332 men and 359 women visiting four different PDCs for their first visits were audited to learn the implementation of ADA recommended guidelines.

3.1.1 Individual PDCs:

These patients came to four different PDCs that were located in different townships of Karachi.

3.1.1.1 PDC1 - was located in Gulshan Township where 248 patients (131 men and 117 women) came during the study period. In PDC1, the screening rates and metabolic outcomes in the patients with type 2 diabetes for different measures was better than the other three PDCs. The screening rates were good for almost all measures, especially for lipid profiles, microalbuminuria, dilated eye examination and lower leg examination. Patients were comparatively better screened for diabetes management and chronic complications at this PDC.

The mean age of patients was 53 ± 10 years; averaged duration of diabetes was 7 years, mean weight 69.7 ± 12.6 kg; mean BMI 27 kg/m^2 and mean BP was 142/88 mmHg. Mean FBG 181 ± 62.7 mg/dl; mean HbA1c $8.96 \pm 1.2\%$; mean TGs 249.6 ± 101.2 mg/dl; mean TCs 194 ± 37.6 mg/dl; mean HDL 38 ± 5.9 mg/dl and mean LDL 116 ± 26.6 mg/dl. Retinopathy seen in 32.6%; nephropathy in 15.03%; hypertension in 64.3%; dyslipidemia in 91.4%; CVD in 7.7%; peripheral neuropathy in 20% and peripheral vascular insufficiency (PVI) in 15%.

3.1.1.2 PDC2 – located in Gulberg Township, 205 patients (87men and 118 women) came for visit. The screening rates were good for HbA1c and diabetes complications. The mean age of patients was 51.41 ± 11 years; averaged duration of diabetes was 6.5 years; mean weight 69 ± 13.5 kg; mean BMI 25.8 kg/m^2 and mean BP was 137/86 mmHg. Mean FBG 182.17 ± 60 mg/dl; mean HbA1c $8.9 \pm 1.6\%$; mean TGs 203.8 ± 145 mg/dl;

mean TCs 193.4 ± 52.2 mg/dl; mean HDL 39.7 ± 4.8 mg/dl and mean LDL 111.14 ± 34.6 mg/dl. Retinopathy seen in 26.3%; nephropathy in 60%; hypertension in 61.3%; dyslipidemia in 74%; CVD in 3.4%; stroke in 0.5%; peripheral neuropathy in 16.3% and PVI in 13.8%.

Table 1 (a): Show the number of patients who were or were not screened for tests and examinations in PDC 1 and PDC 2

PDC1 (N= 248)

PDC2 (N=205)

Variables	Screened / Documented		Not screened / Missing		Referred		Screened / Documented		Not screened / Missing		Referred	
	N	%	N	%	N	%	N	%	N	%	N	%
Age	247	99.6	1	0.4	-	-	197	96.1	8	3.9	-	-
Duration of DM	240	96.8	8	3.2	-	-	188	91.7	17	8.3	-	-
Family history of DM	248	100.0	-	-	-	-	204	99.5	1	0.5	-	-
Tobacco consumption	248	100.0	-	-	-	-	195	95.1	10	4.9	-	-
Weight	247	99.6	1	0.4	-	-	174	84.9	31	15.1	-	-
Height	247	99.6	1	0.4	-	-	147	71.7	58	28.3	-	-
BMI	247	99.6	1	0.4	-	-	146	71.2	59	28.8	-	-
BP	238	96.0	10	4.0	-	-	119	58.0	86	42.0	-	-
FBG	144	58.1	104	41.9	-	-	92	44.9	113	55.1	-	-
RBG	216	87.1	32	12.9	-	-	108	52.7	97	47.3	-	-
HbA1c	162	65.3	86	34.7	-	-	46	22.4	152	74.1	7	3.4
TGs	145	58.5	103	41.5	-	-	36	17.6	168	82.0	1	0.5
TCs	149	60.1	99	39.9	-	-	45	22.0	159	77.6	1	0.5
HDL	143	57.7	105	42.3	-	-	36	17.6	168	82.0	1	0.5
LDL	143	57.7	105	42.3	-	-	36	17.6	168	82.0	1	0.5
S. Creatinine	165	66.5	82	33.1	1	0.4	61	29.8	138	67.3	6	2.9
Urine analysis	15	6.0	232	93.5	1	0.4	46	22.4	155	75.6	4	2.0
Microalbuminuria	126	50.8	122	49.2	-	-	40	19.5	165	80.5	-	-
24 hrs urinary protein	8	3.2	239	96.4	1	0.4	2	1.0	203	99.0	-	-
24 hrs creatinine clear.	4	1.6	244	98.4	-	-	1	0.5	204	99.5	-	-
Fundoscopy	145	58.5	103	41.5	-	-	26	12.7	179	87.3	-	-
Foot examination: For Foot Ulcer	248 (7)	100.0	-	-	-	-	205 (0)	100.0	-	-	-	-
For pulses: Popliteal	230	92.7	18	7.3	-	-	87	42.4	118	57.6	-	-
Post. tibialis	230	92.7	18	7.3	-	-	94	45.9	111	54.1	-	-
Dorsalis pedis	230	92.7	18	7.3	-	-	94	45.9	111	54.1	-	-
For vibrations	210	84.7	38	15.3	-	-	85	41.5	120	58.5	-	-
For touch sensation	210	84.7	38	15.3	-	-	86	42.0	119	58.0	-	-
For reflexes: (Knee)	210	84.7	38	15.3	-	-	83	41.5	122	59.5	-	-
(Ankle)	210	84.7	38	15.3	-	-	86	42.0	119	58.0	-	-

Table 1 (b): Show the number of patients who were or were not screened for tests and examinations in PDC 3 and PDC 4

PDC3 (N=144)

PDC4 (N=94)

Variables	Screened / Documented		Not screened / Missing		Referred		Screened / Documented		Not screened / Missing		Referred	
	N	%	N	%	N	%	N	%	N	%	N	%
Age	142	98.6	2	1.4	-	-	93	98.9	1	0.1	-	-
Duration of DM	142	98.6	2	1.4	-	-	94	100.0	-	-	-	-
Family history of DM	135	93.8	9	6.2	-	-	93	98.9	1	0.1	-	-
Tobacco consumption	144	100.0	-	-	-	-	84	89.4	10	10.6	-	-
Weight	131	91.0	13	9.0	-	-	69	73.4	25	26.6	-	-
Height	127	88.2	17	11.8	-	-	66	70.2	28	29.8	-	-
BMI	127	88.2	17	11.8	-	-	65	69.1	29	30.9	-	-
BP	143	99.3	1	0.7	-	-	93	98.9	1	0.1	-	-
FBG	74	51.4	70	48.6	-	-	58	61.7	36	38.3	-	-
RBG	125	86.8	19	13.2	-	-	86	91.5	8	8.5	-	-
HbA1c	46	31.9	92	63.9	6	4.2	54	57.4	40	42.6	-	-
TGs	64	44.4	75	52.1	5	3.5	52	55.3	33	35.1	9	9.6
TCs	70	48.6	69	47.9	5	3.5	56	59.6	38	40.4	-	-
HDL	62	43.0	77	53.5	5	3.5	50	53.2	35	37.2	9	9.6
LDL	66	45.8	73	50.7	5	3.5	50	53.2	35	37.2	9	9.6
S. Creatinine	96	66.7	41	28.5	7	4.9	65	69.1	19	20.2	10	10.6
Urine analysis	79	54.8	59	41.0	6	4.2	52	55.3	31	33.0	11	11.7
Microalbuminuria	3	0.7	141	99.3	-	-	3	3.2	91	96.8	-	-
24 hrs urinary protein	2	1.4	141	97.9	1	0.7	6	6.4	87	92.6	1	1.1
24 hrs creatinine clear.	1	0.8	142	98.4	1	0.8	5	5.3	88	93.6	1	1.1
Fundoscopy	16	11.1	125	86.8	3	2.1	24	25.5	69	73.4	1	1.1
Foot examination: For Foot Ulcer	144 (4)	100.0	-	-	-	-	94 (3)	100.0	-	-	-	-
For pulses: Popliteal	-	-	144	100.0	-	-	1	1.1	93	98.9	-	-
Post. tibialis	-	-	144	100.0	-	-	1	1.1	93	98.9	-	-
Dorsalis pedis	-	-	144	100.0	-	-	1	1.1	93	98.9	-	-
For vibrations	-	-	144	100.0	-	-	1	1.1	93	98.9	-	-
For touch sensation	-	-	144	100.0	-	-	1	1.1	93	98.9	-	-
For reflexes: (Knee)	-	-	144	100.0	-	-	1	1.1	93	98.9	-	-
(Ankle)	-	-	144	100.0	-	-	1	1.1	93	98.9	-	-

Table 2 (a): Show the number of patients screened or not screened for diabetes management and complications at PDC1 and PDC2

PDC1 (N=248)

PDC2 (N=205)

Variables	Screened / Documented		Not screened / Missing		Screened / Documented		Not screened / Missing	
	N	%	N	%	N	%	N	%
Management:								
Aspirin	248	100	-	-	205	100	-	-
ACE	240	96.8	8	3.2	140	68.3	65	31.7
Anti HTN	238	96	10	4	119	58	86	42
Statin	151	60.9	97	39.1	48	23.4	157	76.6
Insulin	248	100	-	-	204	99.5	-	-
Complications:								
Retinopathy	147	59.3	101	40.7	38	18.5	167	81.5
Nephropathy	133	53.6	115	46.4	195	95.1	10	4.9
Hypertension	248	100	-	-	119	58	86	42
Hyperlipidemia	248	100	-	-	46	22.4	159	77.6
CVD	207	83.5	41	16.5	205	100	-	-
Stroke	216	87.1	32	12.9	205	100	-	-
Peripheral Neuropathy	169	68.1	79	31.9	49	23.9	156	76.1
Peripheral Vascular Insufficiency	229	92.3	19	7.7	87	42.4	118	57.6

3.1.1.3 PDC3 - located in Orangi Township, 144 patients (68 men and 76 women) visited it. The screening rates were good for BP and diabetes management. Patients were not screened for peripheral vascular insufficiency.

The mean age of patients was 48 ± 9.5 years; averaged duration of diabetes was more than 2 years, mean weight 64.3 ± 12.2 kg; mean BMI 26 kg/m^2 and mean BP was 135/84 mmHg. Mean FBG 224.5 ± 79 mg/dl; mean HbA1c $9.4 \pm 2.1\%$; mean TGs 186 ± 109 mg/dl; mean TCs 201.2 ± 47 mg/dl; mean HDL 41.45 ± 9.6 mg/dl and mean LDL 125.3 ± 37.3 mg/dl. Retinopathy seen in 40%; nephropathy in 71.4%; hypertension in 50%; dyslipidemia in 83% and CVD in 3.5%.

Table 2 (b): Show the number of patients screened or not screened for diabetes management and complications at PDC3 and PDC4

PDC3 (N=144)

PDC4 (N=94)

Variables	Screened / Documented		Not screened / Missing		Screened / Documented		Not screened / Missing	
	N	%	N	%	N	%	N	%
Management:								
Aspirin	144	100	-	-	94	100	-	-
ACE	143	99.3	1	0.7	93	98.9	1	1.1
Anti HTN	143	99.3	1	0.7	93	98.9	1	1.1
Statin	74	51.4	70	48.6	59	62.8	35	37.2
Insulin	248	100	-	-	94	100	-	-
Complications:								
Retinopathy	15	10.4	129	89.6	24	25.5	70	74.5
Nephropathy	7	4.9	137	95.1	9	9.6	85	90.4
Hypertension	143	99.3	1	0.7	93	98.9	1	1.1
Hyperlipidemia	71	49.3	73	50.7	58	61.7	36	38.3
CVD	111	77.1	33	22.9	84	89.4	10	10.6
Stroke	109	75.7	35	24.3	94	100	-	-
Peripheral Neuropathy	64	44.4	80	55.6	41	43.6	53	56.4
Peripheral Vascular Insufficiency	-	-	144	100	1	1.1	93	98.9

Table 3 (a): Means of anthropometric and biochemical parameters of T2DM subjects in PDC 1 and PDC 2

Variables	Total N=248 PDC1	Mini.	Maxi.	Mean	2 Std Dev. ±	Total N=205 PDC2	Mini.	Maxi.	Mean	2 Std Dev. ±
Age	247	30.0	84.0	52.5	9.9	197	20.0	80.0	51.4	10.9
Weight	247	41.0	117.0	69.7	12.6	174	43.0	132.0	68.9	13.5
Height	247	142.0	187.0	160.8	8.9	147	141.0	184.0	163.6	9.7
BMI	247	17.0	48.9	26.9	4.3	146	15.2	44.3	25.8	4.7
DBP	238	60.0	120.0	87.7	11.1	119	70.0	120.0	85.5	8.1
SBP	238	80.0	210.0	142.0	23.1	119	100.0	200.0	137.3	17.6
FBG	144	60.0	390.0	181.5	62.7	92	76.0	379.0	182.1	59.5
RBG	216	78.0	900.0	283.1	106.6	108	86.0	474.0	264.5	84.8
HbA1c	162	5.7	13.1	8.9	1.2	46	6.0	12.8	8.9	1.6
TGs	145	62.0	700.0	249.6	101.2	36	44.0	758.0	203.8	145.4
TCs	149	90.0	345.0	194.1	37.6	45	128.0	410.0	193.4	52.2
HDL	143	24.0	67.0	37.9	5.8	36	32.0	57.0	39.7	4.8
LDL	143	58.0	243.0	115.98	26.6	36	60.0	205.0	111.1	34.6
S. Creatinine	165	.6	9.0	1.1	.6	61	.5	1.5	.9	.2
Microalbuminuria	122	50.0	535.0	150.7	102.7	4	32.0	116.0	87.0	37.4
24 hrs U. protein	8	90.0	190.0	123.7	33.7	2	435.0	850.0	642.5	293.4
24 hrs Creat. Clear.	4	50.0	109.0	71.0	26.1	1	354.0	354.0	354.0	.

Table 3 (b): Means of anthropometric and biochemical parameters of T2DM subjects in PDC 3 and PDC 4

Variables	Total N=144 PDC3	Mini.	Maxi.	Mean	2 Std Dev. ±	Total N=94 PDC4	Mini.	Maxi.	Mean	2 Std Dev. ±
Age	142	23.0	72.0	47.9	9.5	93	26.0	86.0	50.1	10.6
Weight	131	40.0	107.0	64.3	12.2	69	41.5	123.0	73.2	16.6
Height	127	136.0	188.0	157.4	9.3	66	138.0	183.0	159.1	10.3
BMI	127	14.1	46.3	26.1	4.5	65	17.5	45.9	28.8	5.8
DBP	143	60.0	120.0	83.5	8.1	93	60.0	100.0	83.2	8.0
SBP	143	90.0	200.0	134.6	17.3	93	110.0	190.0	134.1	15.0
FBG	74	75.0	416.0	224.5	79.1	58	80.0	408.0	206.7	80.8
RBG	125	92.0	593.0	287.2	103.8	86	76.0	557.0	274.2	98.9
HbA1c	46	5.0	13.8	9.4	2.1	54	5.8	13.8	9.5	2.0
TGs	64	36.0	558.0	186.9	109.0	52	73.0	743.0	212.1	137.1
TCs	70	95.0	344.0	201.1	46.9	56	106.0	376.0	185.9	41.9
HDL	62	24.0	93.0	41.4	9.6	50	23.0	61.0	39.2	7.3
LDL	66	48.0	205.0	125.3	37.3	50	51.0	248.0	116.8	30.6
S. Creatinine	96	.5	2.0	.91	.2	65	.6	2.7	1.0	.3
Microalbuminuria	2	20.0	100.0	60.0	56.5	2	100.0	173.0	136.5	51.6
24 hrs U. protein	2	216.0	270.0	243.0	38.1	6	120.0	672.0	287.3	201.6
24 hrs Creat. Clear.	1	73.0	73.0	73.0	.	5	71.0	98.0	84.9	11.2

Table 4: shows patients within different PDCs with parameters for good diabetes control

Variables (Mean Values)	PDC1	Mean	2 Std Dev. ±	PDC2	Mean	2 Std Dev. ±	PDC3	Mean	2 Std Dev. ±	PDC4	Mean	2 Std Dev. ±
Age (years)	√	52.6	9.9	-	-	-	-	-	-	-	-	-
BMI (kg/m ²)	-	-	-	√	25.8	4.7	-	-	-	-	-	-
BP (mm Hg)	-	-	-	-	-	-	-	-	-	√	134/83	-
FBG (mg/dl)	√	181.5	62.7	-	-	-	-	-	-	-	-	-
RBG (mg/dl)	-	-	-	√	264.5	84.8	-	-	-	-	-	-
HbA1c (%)	-	-	-	√	8.9	1.6	-	-	-	-	-	-
TGs (mg/dl)	-	-	-	-	-	-	√	186.9	109	-	-	-
TCs (mg/dl)	-	-	-	-	-	-	-	-	-	√	185.9	41.9
HDL (mg/dl)	-	-	-	-	-	-	√	41.5	9.6	-	-	-
LDL (mg/dl)	-	-	-	√	111.14	34.6	-	-	-	-	-	-
S. Creatinine (mg/dl)	-	-	-	-	-	-	√	0.9	0.26	-	-	-
Microalbuminuria (mg/dl)	-	-	-	-	-	-	√	60	56.5	-	-	-

Table 5: Shows patients within different individual PDCs with parameters for poor diabetes control

Variables	PDC1	Mean	2 Std Dev. \pm	PDC2	Mean	2 Std Dev. \pm	PDC3	Mean	2 Std Dev. \pm	PDC4	Mean	2 Std Dev. \pm
Age (years)	-	-	-	-	-	-	√	48	9.5	-	-	-
BMI (kg/m ²)	-	-	-	-	-	-	-	-	-	√	28.8	5.8
BP (mm Hg)	√	142/88	-	-	-	-	-	-	-	-	-	-
FBG (mg/dl)	-	-	-	-	-	-	√	224.5	79.1	-	-	-
RBG (mg/dl)	-	-	-	-	-	-	√	287.2	103.9	-	-	-
HbA1c (%)	-	-	-	-	-	-	-	-	-	√	9.5	2
TGs (mg/dl)	√	249.6	101.2	-	-	-	-	-	-	-	-	-
TCs (mg/dl)	-	-	-	-	-	-	√	201.1	46.9	-	-	-
HDL (mg/dl)	√	38	5.8	-	-	-	-	-	-	-	-	-
LDL (mg/dl)	-	-	-	-	-	-	√	125.3	37.3	-	-	-
S. Creatinine (mg/dl)	√	1.1	0.6	-	-	-	-	-	-	-	-	-
Microalbuminuria (mg/dl)	-	-	-	-	-	-	-	-	-	√	136.5	51.6

3.1.1.4 PDC4 – located in Liaquatabad Township was visited by 94 patients (46 men and 48 women) during the study period. The screening rates were good for serum creatinine and diabetes management. Only one patient was screened for peripheral vascular insufficiency.

The mean age of patients was 50 ± 10.6 years; averaged duration of diabetes was 2 years, mean weight 73.3 ± 16.6 kg; mean BMI 28.8 kg/m^2 and mean BP was 134/83 mmHg. Mean FBG 206 ± 81 mg/dl; mean HbA1c $9.6 \pm 2\%$; mean TGs 212.12 ± 137.2 mg/dl; mean TCs 186 ± 42 mg/dl; mean HDL 39.2 ± 7.3 mg/dl and mean LDL 116.8 ± 30.6 mg/dl. Retinopathy was seen in 25%; nephropathy in 56%; hypertension in 58%; dyslipidemia in 76% and CVD in 10.7%.

From the medical records the following variables were reviewed in all the PDCs:

Table 6: Shows patients within different individual PDCs with good (G) and poor (P) screening of variables

Variables	PDC 1	N= 248	%	PDC 2	N= 205	%	PDC 3	N= 144	%	PDC 4	N= 94	%
Age (years)	(G)*	-	99.6	(P)*	-	96.1	-	-	-	-	-	-
Weight (kg)	(G)	-	99.6	-	-	-	-	-	-	(P)	-	73.4
Height (cm)	(G)	-	99.6	-	-	-	-	-	-	(P)	-	70.2
BMI (kg/m ²)	(G)	-	99.6	(P)	-	59.0	-	-	-	-	-	-
BP (mm Hg)	-	-	-	(P)	-	58.0	(G)	-	99.3	-	-	-
HbA1c (%)	-	-	-	(G)	-	74.1	(P)	-	31.9	-	-	-
Lipid Profile mg/dl	(G)	-	58.5	(P)	-	18.7	-	-	-	-	-	-
S. Creatinine (mg/dl)	-	-	-	(P)	-	29.8	-	-	-	(G)	-	69.1
Urine Detailed Report (DR)	(P)	-	6.0	-	-	-	-	-	-	(G)	-	55.3
Microalbuminuria (mg/dl)	(G)	-	50.8	-	-	-	(P)	-	0.7	-	-	-
Fundoscopy	(G)	-	58.5	-	-	-	(P)	-	11.1	-	-	-
Lower Leg (LL) examination	(G)	-	88.1	-	-	-	(P)	-	0	(P)	-	0
Aspirin	(G)	-	100.0	(G)	-	100.0	(G)	-	100.0	(G)	-	100.0
ACE inhibitors	-	-	-	(P)	-	68.3	(G)	-	99.3	-	-	-
Anti Hypertensive	-	-	-	(P)	-	58.0	(G)	-	99.3	-	-	-
Statin	-	-	-	-	-	-	-	-	-	(G)	-	62.8
Insulin	(G)	-	-	(G)	-	-	(G)	-	-	(G)	-	-

(G)* = Good; (P)* = Poor

Table 7: Screening for Diabetes Complications within different individual PDCs

Variables	PDC 1	Total N= 248	%	PDC 2	Total N= 205	%	PDC 3	Total N= 144	%	PDC 4	Total N= 94	%
Retinopathy	(G)	-	59.3	-	-	-	(P)	-	10.4	-	-	-
Nephropathy	-	-	-	(G)	-	95.1	(P)	-	4.9	-	-	-
Hypertension	(G)	-	100.0	(P)	-	58.0	-	-	-	-	-	-
Hyperlipidemia	(G)	-	100.0	(P)	-	22.4	-	-	-	-	-	-
CVD	-	-	-	(G)	-	100.0	(P)	-	77.1	-	-	-
Stroke	-	-	-	(G)	-	100.0	(P)	-	75.7	(G)	-	100.0
Peripheral Neuro.	(G)	-	68.1	(P)	-	23.9	-	-	-	-	-	-
Peripheral Vascular Insuff.	(G)	-	92.3	-	-	-	(P)	-	0	(P)	-	0

Tables 8 and 9: Show the number of T2DM patients who were or were not screened for tests and examinations in all PDCs according to ADA guidelines.

Table 8:

Variables (Total n=691)	Screened or Documented		Not screened or Missing		Referred	
	N	%	N	%	N	%
Age	679	98.3	12	1.7	-	-
Duration of DM	665	96.0	26	3.9	-	-
Family history of DM	680	98.4	11	1.6	-	-
Tobacco consumption	671	97.1	20	2.9	-	-
Weight	621	90.0	70	10	-	-
Height	587	85.0	104	15	-	-
BMI	585	84.7	106	15.3	-	-
BP	593	86.0	98	14	-	-
FBG	368	53.3	323	46.7	-	-
RBG	535	77.4	156	22.6	-	-
HbA1c	308	44.6	353	51.1	30	4.3
TGs	297	43.0	379	54.8	15	2.2
TCs	319	46.2	358	51.8	14	2.0
HDL	291	42.1	385	55.7	15	2.2
LDL	295	42.7	381	55.1	15	2.2
S. Creatinine	387	56.0	280	40.5	24	3.5
Urine analysis	192	27.8	477	69	22	3.2
Microalbuminuria	172	25.0	519	75	-	-
24 hrs urinary protein	18	2.6	670	97	3	0.4
24 hrs creatinine clear.	11	1.6	678	98.1	2	0.3
Fundoscopy	211	30.5	476	69	4	0.5
Foot examination: For Foot Ulcer	691 (14)	100.0	-	-	-	-
For pulses: Popliteal	317	46.0	374	54.0	-	-
Post. tibialis	325	47.0	366	53.0	-	-
Dorsalis pedis	325	47.0	366	53.0	-	-
For vibrations	296	42.8	395	57.2	-	-
For touch sensation	297	43.0	394	57.0	-	-
For reflexes: (Knee)	294	42.5	397	57.5	-	-
(Ankle)	297	43.0	394	57.0	-	-

Table 9:

Variables (Total n=691)	Screened or Documented		Not screened or Missing		Referred	
	N	%	N	%	N	%
Management:						
Aspirin	691	100	-	-	-	-
ACE	616	89.1	75	10.9	-	-
Anti HTN	593	86.0	98	14.0	-	-
Statin	332	48.0	359	52.0	-	-
Insulin	691	100.0	-	-	-	-
Complications:						
Retinopathy	224	32.4	467	67.6	-	-
Nephropathy	159	23.0	532	77.0	-	-
Hypertension	593	86.0	98	14.0	-	-
Hyperlipidemia	326	47.2	365	52.8	-	-
CVD	607	87.8	84	12.2	-	-
Stroke	624	90.3	67	9.7	-	-
Peripheral Neuropathy	631	91.3	60	8.7	-	-
Peripheral Vascular Insufficiency	317	45.9	374	54.1	-	-

Table 10: Frequency distribution of variables in all PDCs

Variables	Screened / Documented For:		Found to have:		Referred	
	N	%	N	%	N	%
Age	679	98.3	-	-	-	-
20-40 years	-	-	125	18.4	-	-
41-60 years	-	-	449	66.1	-	-
≥61 years	-	-	105	15.5	-	-
Duration of DM	665	96.0	-	-	-	-
<2 years	-	-	167	25.1	-	-
2-10 years	-	-	342	51.4	-	-
>10 years	-	-	156	23.5	-	-
Family history of DM	680	98.4	-	-	-	-
Yes	-	-	407	59.0	-	-
Tobacco consumption	671	97.1	-	-	-	-
Non-smokers	-	-	593	88.4	-	-
Ex-smokers	-	-	17	2.5	-	-
Smokers	-	-	34	5.1	-	-
Tobacco chewing	-	-	27	4.0	-	-
BMI	585	84.7	-	-	-	-
<25 kg/m ²	-	-	108	18.5	-	-
>25 kg/m ²	-	-	354	60.5	-	-

Variables	Screened / Documented For:		Found to have:		Referred	
	N	%	N	%	N	%
BP	593	86.0	-	-	-	-
≤130/80 mmHg	-	-	265	44.7	-	-
>130/80 mmHg	-	-	328	55.3	-	-
FBG	368	53.3	-	-	-	-
<130 mg/dl	-	-	60	16.3	-	-
>130 mg/dl	-	-	308	83.7	-	-
RBG	535	77.4	-	-	-	-
≤200 mg/dl	-	-	114	21.3	-	-
>200 mg/dl	-	-	421	78.7	-	-
HbA1c	308	44.6	-	-	30	4.3
<7 %	-	-	31	10.06	-	-
>7 %	-	-	277	90.0	-	-
TGs	297	43.0	-	-	15	2.2
≤150 mg/dl	-	-	89	30.0	-	-
>150 mg/dl	-	-	208	70.0	-	-
TCs	319	46.2	-	-	14	2.0
≤200 mg/dl	-	-	190	59.6	-	-
>200 mg/dl	-	-	129	40.4	-	-
HDL	291	42.1	-	-	15	2.2
<40 mg/dl	-	-	142	48.8	-	-
≥40 mg/dl	-	-	139	47.8	-	-
≥50	-	-	10	3.4	-	-
LDL	295	42.7	-	-	15	2.2
≤100 mg/dl	-	-	94	39.1	-	-
>100 mg/dl	-	-	201	68.9	-	-
S. Creatinine	387	56.0	-	-	24	3.5
≤1.2 mg/dl	-	-	337	87.1	-	-
>1.2 mg/dl	-	-	50	12.9	-	-
Urine analysis	192	27.8	-	-	22	3.2
Normal	-	-	83	43.2	-	-
Abnormal	-	-	109	56.8	-	-
Microalbuminuria	172	25.0	-	-	-	-
Yes	-	-	129	75.0	-	-
Negative	-	-	43	25.0	-	-
Fundoscopy	211	30.5	-	-	4	0.5
Pathologic changes	-	-	67	31.8	-	-
Foot examination: For Foot Ulcer	691	100.0	14	2.0	-	-

Table 11: Cut off values for biochemical variables according to ADA guidelines

Variables	Total n	Percent %	Mean	2 Std. Dev.
Fasting Blood Glucose (FBG) (mg/dl)	368	-	194.32	70.5
<130 mg/dl	60	16.3	-	-
≤ 200 mg/dl	166	45.1	-	-
>200 mg/dl	142	38.6	-	-
HbA1c	308	-	9.13	1.6
≤ 7	31	10.1	-	-
>7	277	89.9	-	-
Cholesterol (mg/dl)	319	-	194.15	42.7
≤200	190	59.6	-	-
>200	129	40.4	-	-
Triglycerides (mg/dl)	297	-	224.00	118.1
≤150	89	30.0	-	-
>150	208	70.0	-	-
Low Density Lipoprotein (LDL) (mg/dl)	295	-	117.62	31.1
≤100	94	31.9	-	-
>100	201	68.1	-	-
High Density Lipoprotein (HDL) (mg/dl)	291	-	39.16	7.1
Male	141	48.5	38.41	7.5
<40 (Low HDL)	78	55.3	-	-
≥40	60	42.6	-	-
≥50	3	2.1	-	-
Female	150	51.5	39.86	6.5
<40 (Low HDL)	64	42.7	-	-
≥40	79	52.7	-	-
≥50	7	4.6	-	-

3.1.2 Age:

Age of 679 (325 men and 354 women) patients was documented, we further grouped them and found that 18.4% were between 20- 40 years of age; 66.1% were between 41-60 years of age and 15.5% were in ≥61 years of age. This indicates that 66.1% patients represent a majority having diabetes aged between 41-60 years. This also reflects that diabetes is affecting mostly those in the productive years of their life.

Table 12: Means of anthropometric and biochemical parameters of T2DM subjects in all PDCs

Variables	Total N=691	Mini.	Maxi.	Mean	2 Standard Deviation ±
Age	679	20.0	86.0	50.9	10.4
Weight	621	40.0	132.0	68.8	13.5
Height	587	136.0	188.0	160.6	9.6
BMI	585	14.0	49.0	26.7	4.7
DBP	593	60.0	120.0	85.5	9.6
SBP	593	80.0	210.0	138.1	19.8
FBG	368	60.0	416.0	194.3	70.5
RBG	535	76.0	900.0	278.8	100.7
HbA1c	308	5.0	13.8	9.1	1.6
TGs	297	36.0	758.0	224.0	118.1
TCs	319	90.0	410.0	194.1	42.7
HDL	291	23.0	93.0	39.1	7.1
LDL	295	48.0	248.0	117.6	31.1
S. Creatinine	387	.5	9.0	1.0	.4
Microalbuminuria	130	20.0	535.0	147.1	101.0
24 hrs U. protein	18	90.0	850.0	249.1	209.0
24 hrs Creat. Clear.	11	50.0	354.0	103.2	84.9

3.1.3 Duration of Diabetes:

A total of 665 patients had given history of duration of diabetes and the average duration of diabetes was 8 years. And of these 51.7% patients had 2-10 years duration of diabetes and 100 patients were aged between 41-60 years with >10 years duration of diabetes.

Table 13: Frequency distribution of duration of DM according to gender in T2DM subjects

Gender	Duration of T2DM			Total
	<2 yrs	2-10 yrs	>10 yrs	
Male	86 27.0%	163 51.1%	70 21.9%	319 48.0%
Female	81 23.4%	179 51.7%	86 24.9%	346 52.0%
Total	167	342	156	665

Table 14: Frequency distribution of duration of DM according to age group in T2DM subjects

Age Group	Duration of T2DM			Total n=655
	<2 yrs	2-10 yrs	>10 yrs	
20-40 years	52 (43.7%)	57 (47.9%)	10 (8.4%)	119
41-60 years	98 (22.5%)	237 (54.5%)	100 (22.9%)	435
≥61 years	15 (14.9%)	42 (41.6%)	44 (43.5%)	101
Total	165	336	154	655

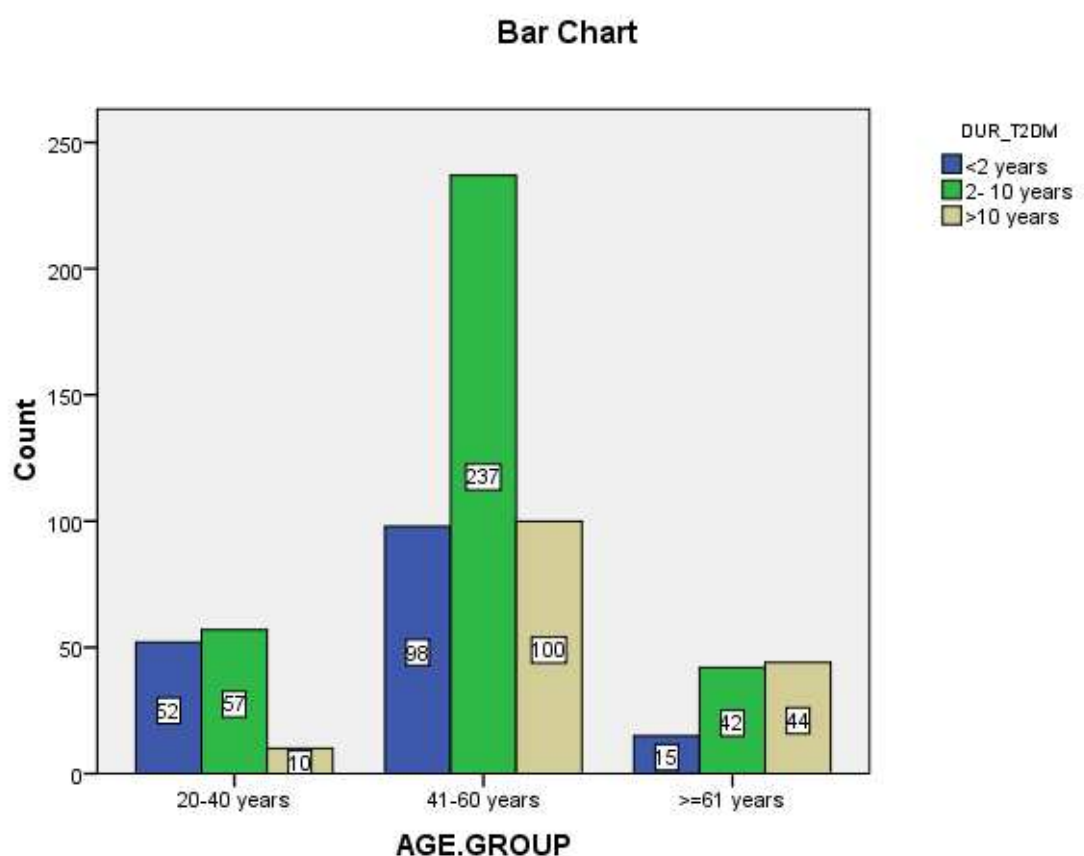


Fig 1: Cluster bars between duration of DM and age group in T2DM at all PDCs

3.1.4 Family History of Diabetes:

Of the 691 records reviewed, positive family history of diabetes was seen in 60% of the patients.

Table 15: Frequency distribution of family history of DM according to age group in T2DM subjects

Age Group	Family History of T2DM			Total
	No	Yes	Not Known	
20-40 years	35	90	-	125
41-60 years	176	265	8	449
≥61 years	53	49	3	105
Total	264	404	11	679

Documented 679 (98.3%) Missing 12 (1.7%)

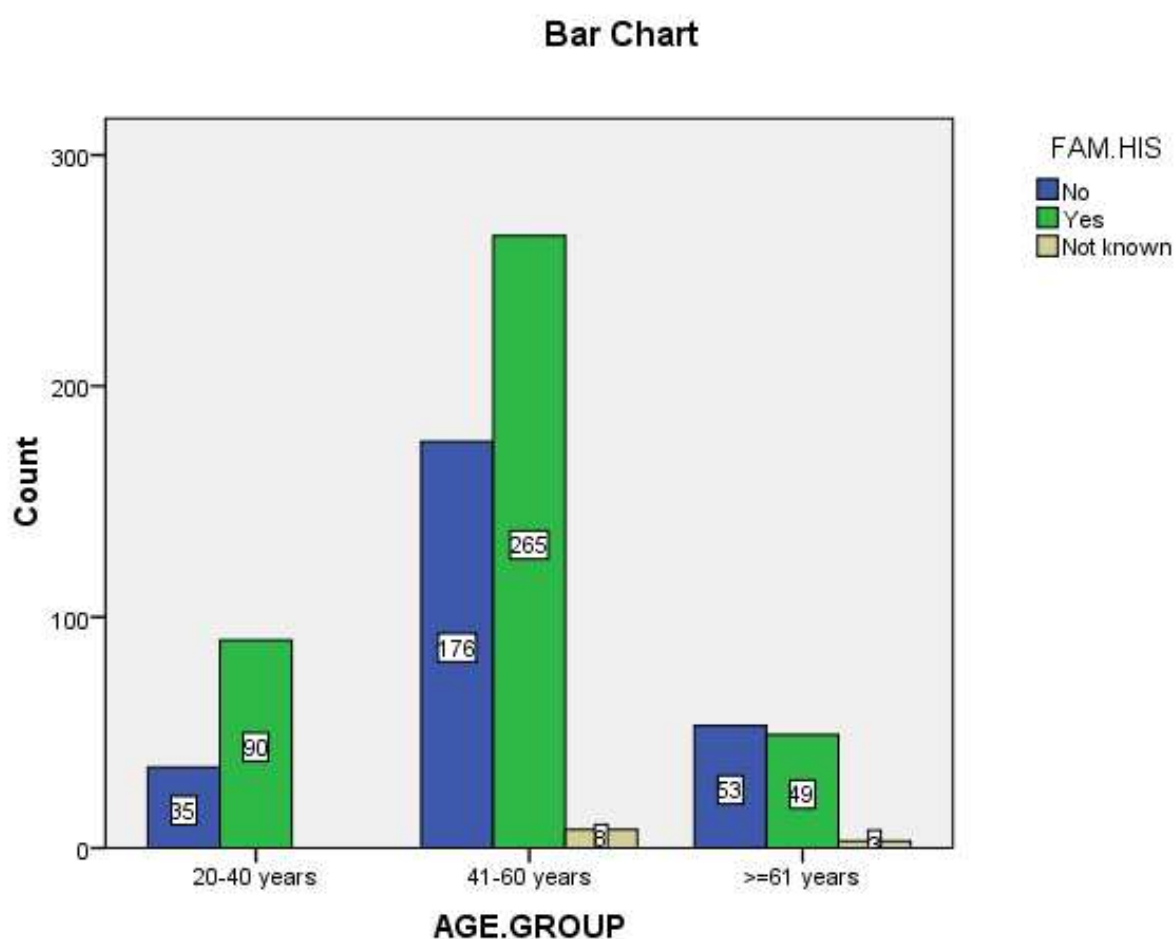


Fig 2: Cluster bars between family history of DM and age group in T2DM at all PDCs

3.1.5 Tobacco Consumption:

The records showed that 86% were nonsmokers. Seventeen patients were ex-smokers, 34 were smokers and 27 had the habit of chewing tobacco in pan.

Table 16: Tobacco consumption in all PDCs

Tobacco consumption	Total	
	n=691	percentage
Non smokers	593	85.8
Smokers	34	4.9
Tobacco chewing	27	3.9
Ex smokers	17	2.5
Not known/Missing	20	2.9
Total	691	100

3.1.6 Body Mass Index:

A total of 585 patients had their BMI measured and of these 7 patients were underweight with a BMI of $<18.5 \text{ kg/m}^2$, 17.2% had normal BMI of $18.5 - 22.9 \text{ kg/m}^2$, 21% were overweight and 60.5% were obese with a BMI of $>25 \text{ kg/m}^2$. Three hundred and fifty-four subjects in all PDCs were obese and of these 42.3% were in the age group 41 – 60 years. Of 293 females who had their BMI measured, 67% were obese with a BMI $>25 \text{ kg/m}^2$ and of 292 males 53.8% were obese.

Table 17: Percentage distribution of BMI according to gender in T2DM subjects in all PDCs

Gender	BMI Group (kg/m ²)				
	Under - weight <18.5	Normal 18.5 -22.9	Overweight 23-25	Obese >25	Total
Male	3 1%	59 20.2%	73 25%	157 53.8%	292 49.9%
Female	4 1.4%	42 14.3%	50 17.1%	197 67.2%	293 50.1%
Total	7	101	123	354	585

Table 18: Frequency distribution of BMI according to age group in T2DM subjects

Age Group	BMI kg/m ²				Total n=577
	<18.5 Unwt.	18.5-22.9 Normal	23-25 Ov.wt	>25 Obese	
20-40 years	1 (14.3%)	20 (20.6%)	23 (18.9%)	64 (18.2%)	108 (18.7%)
41-60 years	5 (71.4%)	56 (57.7%)	76 (62.3%)	244 (69.5%)	381 (66.0%)
≥ 61 years	1 (14.3%)	21 (21.6%)	23 (18.9%)	43 (12.3%)	88 (15.3%)
Total	7	97	122	351	577

Documented 577 and Missing 114

The above table shows that 351 (60.8%) subjects in all PDCs were obese and of these 244 (69.5%) were in the age group 41 – 60 years.

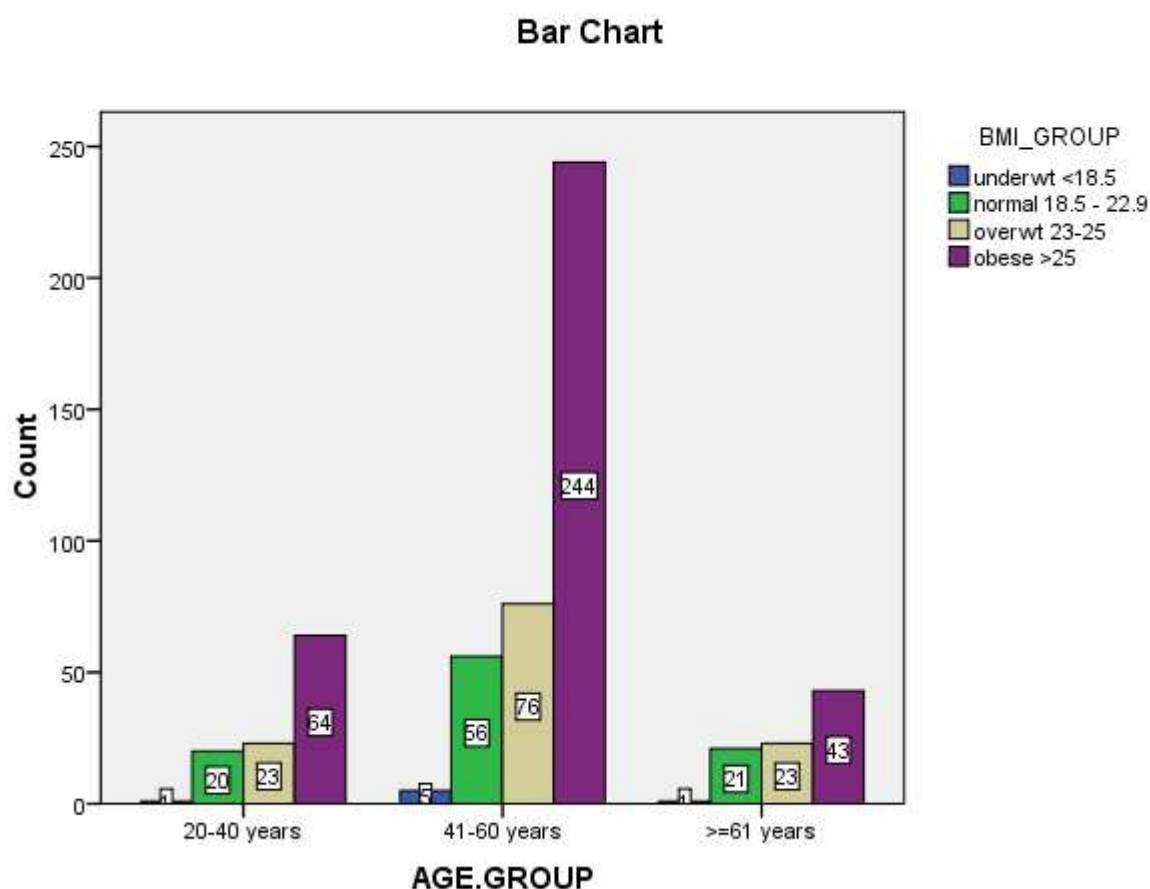


Fig 3: Cluster bars between BMI and age group in T2DM at all PDCs

3.1.7 Blood Pressure:

The blood pressure of 593 patients was documented and of these 285 were males and 308 females. Patients with type 2 diabetes had an average BP level of 138/86 mmHg. Of 593 patients, normal diastolic BP ≤ 80 mm Hg was seen in 49% patients and high diastolic BP > 80 mm Hg recorded in 51% patients. Normal systolic BP ≤ 130 mm Hg was seen in 61.2% and high systolic BP > 130 mm Hg in 38.8%. In 35.3% patients, diastolic BP ≥ 90 mm Hg was documented and 33.1% patients showed systolic BP ≥ 140 mm Hg. A total of 44.7% patients (140 men and 125 women) had BP $\leq 130/80$ mm Hg and 328 (55.3%) patients (145 men and 183 women) had BP $> 130/80$ of mm Hg. The data on blood pressure showed that high blood pressure ($\geq 130/80$ mm Hg) was more in women than men.

Table 19: DBP and SBP recorded in different age groups of T2DM subjects in all PDCs

Age Group	Normal DBP ≤ 80 mm Hg	Hypertensive DBP > 80 mm Hg	Normal SBP ≤ 130 mm Hg	Hypertensive SBP > 130 mm Hg	Total
20-40 years	61 58.1%	44 41.9%	78 74.3%	27 25.7%	105
41-60 years	187 47.6%	206 52.4%	241 61.3%	152 38.7%	393
≥ 61 years	37 43.5%	48 56.5%	38 44.7%	47 55.3%	85
Total	357 61.2%	226 38.8%	357 61.2%	226 38.8%	583

Table 20: Percentage of hypertension recorded in different age groups of T2DM subjects

Age Group	Normal BP ≤130/80 mm Hg	Hypertensive BP >130/80 mm Hg	Total
20-40 years	62 59%	43 41%	105
41-60 years	170 43.3%	223 56.7%	393
≥ 61 years	29 34.1%	56 65.9%	85
Total	261 44.8%	322 55.2%	583

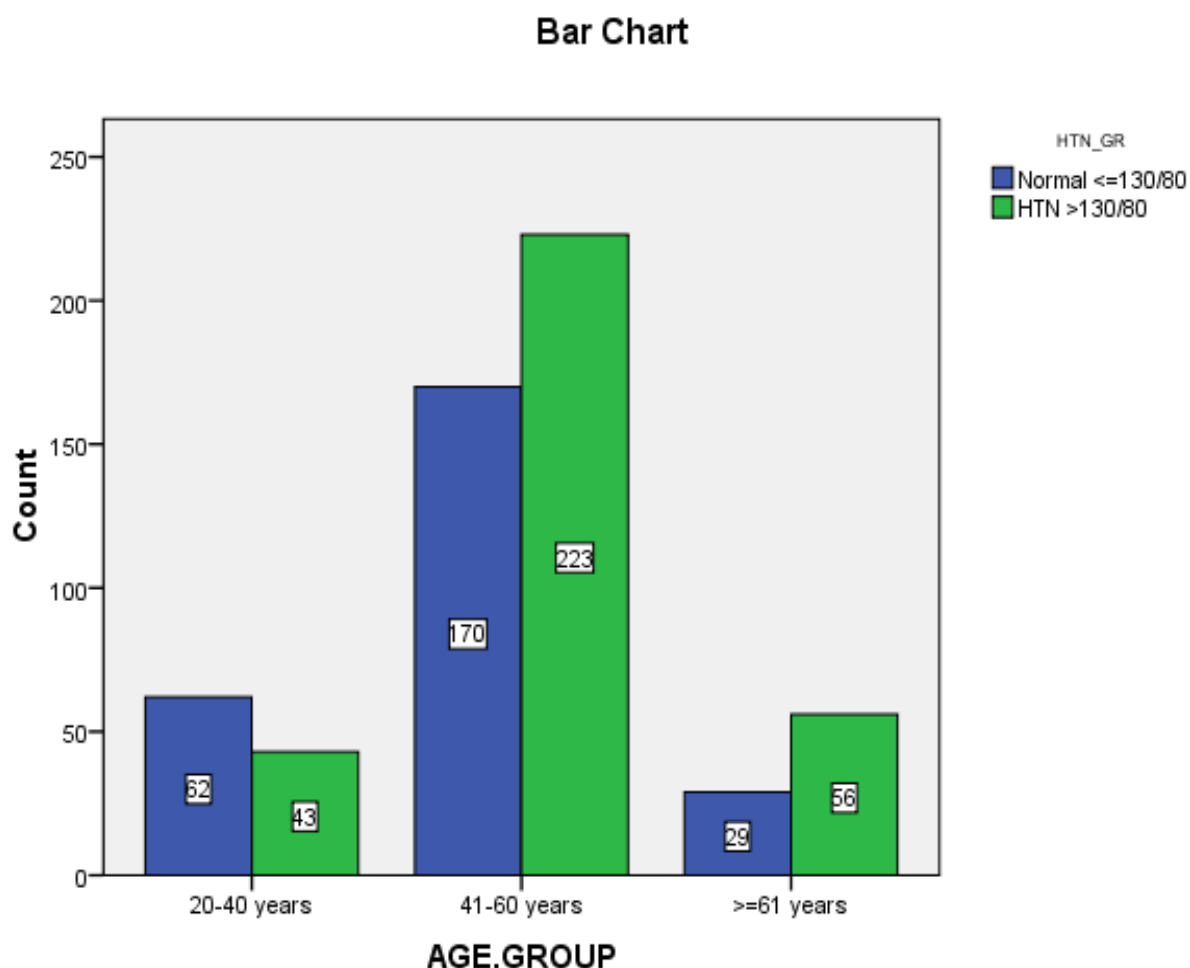


Fig 4: Cluster bars between hypertension and age group in T2DM at all PDCs

Table 21: Percentage distribution of normotensive and hypertensive BP according to gender in T2DM subjects

Gender	BP \leq130/80 mm Hg	BP $>$130/80 mm Hg	Total N=593
Male	140 49.1%	145 50.9%	285
Female	125 40.6%	183 59.4%	308
Total	265 44.7%	328 55.3%	593

3.1.8 Fasting Blood Glucose:

A total of 368 patients had their FBG measured, of which 40 had FBG between 80-120 mg/dl and 325 had FBG levels $>$ 120 mg/dl. The fasting blood glucose level averaged 194.32 ± 70.59 in these patients.

Table 22: Distribution of FBG according to gender in all PDCs

Gender	FBG mg/dl			
	<80	80-120	>120	Total
Male	1	20	163	184
Female	2	20	162	184
Total	3	40	325	368

3.1.9 Random Blood Glucose:

A total of 535 had RBG measured and 114 had RBG levels \leq 200 mg/dl. In these patients, random blood glucose level averaged 278.86 ± 100.76 mg/dl (15.49 mmol/l).

3.1.10 HbA1c:

HbA1c was measured in 308 patients and HbA1c of ≤ 7 seen in 10.15% >7 and ≤ 8 in 14.6%, and >8 in 75.3% patients. Thirty patients were referred for HbA1c tests. In these patients the HbA1c level averaged $9.1 \pm 1.6\%$. HbA1c levels of >9 was seen in 30.2% of patients on insulin.

Table 23: Frequency distribution of HbA1c in T2DM subjects

HbA1c (%)	Total n=308 %	
≤ 7 (Good)	31	10.1
$>7 \leq 8$ (Fair)	45	14.6
$>8 \leq 9$ (Poor)	93	30.2
>9 (Bad)	139	45.1
Total	308	100

Screened 308(44.5%) Missing 383 (55.5%)

Table 24: Percentage distribution of HbA1c according to age

Age Group	HbA1c ≤ 7	HbA1c > 7	Total
20-40 years	5 9.8%	46 90.2%	51
41-60 years	20 9.9%	183 90.1%	203
≥ 61 years	6 11.3%	47 88.7%	53
Total	31 10.1%	276 89.9%	307

3.1.11 Lipid Profiles:

Lipid profile showed that 297 patients had their triglycerides checked and of these 147 were men and 150 were women. In 30% patients triglycerides was ≤ 150 mg/dl and in 70% triglycerides was >150 mg/dl. Total cholesterol was checked in 319 patients (156 men and 163 women). In 190 (59.5%) cholesterol level was ≤ 200 mg/dl and in 129 (40%) >200 mg/dl was recorded. Total Cholesterol to HDL ratio (TC/HDL Ratio) (52) calculated in a total of 287 patients of which 140 were male. In these

male patients 11 had a ratio of <3.4 (very low risk), 12 had a ratio of 4.0 (low risk), 48 had a ratio of 5.0 (average risk), 69 had a ratio of 9.5 (moderate risk) and none had a ratio of >23 (high risk). TC/HDL Ratio calculated in 147 female and of these 11 had TC/HDL ratio >3.3 (very low risk), 15 had a ratio 3.8 (low risk), 30 had a ratio 4.5 (average risk), 89 had a ratio of 7.0 (moderate risk) and 02 had a ratio of >11 (high risk). In a total of 291 patients the HDL levels was recorded and in men HDL level ≤ 40 mg/dl found in 107 (36.7%) and >40 mg/dl in 34 (11.7%). In women, HDL level of ≤ 50 mg/dl recorded in 145 (49.8%) and >50 mg/dl in only 5 (1.7%). In 295 patients, 32% had LDL levels ≤ 100 mg/dl and LDL >100mg/dl found in 68% patients. Fourteen patients were referred for lipid tests. Overall undesirable lipid profiles were seen more in men as compared to women. Patients with type 2 diabetes had an average cholesterol level of 194 mg/dl (2.18 mmol/l), an average triglyceride level of 224 mg/dl (2.52 mmol/l), an average HDL cholesterol level of 39 mg/dl (1 mmol/l), and an average LDL cholesterol level of 117 mg/dl (3 mmol/l).

Table 25: Overall lipid profile of T2DM at all PDCs

Triglycerides	Frequency n=691	Percentage
Test not done	379	54.8
Test done	297	43.0
Advised	15	2.2
Total	691	100.0
Total cholesterol		
Test not done	357	51.7
Test done	320	46.3
Advised	14	2.0
Total	691	100.0
HDL		
Test not done	385	55.7
Test done	291	42.1
Advised	15	2.2
Total	691	100.0
LDL		
Test not done	381	55.1
Test done	295	42.7
Advised	15	2.2
Total	691	100.0

Table 26: Percentage distribution of Lipid profile according to gender

Gender	TGs mg/dl		TC mg/dl		HDL mg/dl		LDL mg/dl	
	≤150	>150	≤200	>200	M ≤40 F ≤50	>40 >50	≤100	>100
Male	35 23.8%	112 76.2%	89 57.1%	67 42.9%	107 36.7%	34 11.7%	40 28.6%	100 71.4%
Female	54 36.0%	96 64.0%	101 62.0%	62 38.0%	145 49.8%	5 1.7%	54 34.8%	101 65.2%
Total	89 30.0%	208 70.0%	190 59.6%	129 40.4%	142 48.8%	149 51.2%	94 31.9%	201 68.1%

3.1.12 Serum Creatinine:

Serum creatinine was checked in 387 patients and 87.1% showed ≤1.2 mg/dl, 12.4% had 1.3 – 2 mg/dl and 0.52% had >2 mg/dl. Twenty four patients were referred for serum creatinine tests.

3.1.13 Urine Analysis:

Urine analysis was recorded in 192 patients and 22 were referred to have the test done.

3.1.14 Microalbuminuria: (30-300 mg/day)

Urine microalbumin screening was recorded in 172 and of these patients 75% had microalbuminuria.

3.1.15 Eye Examination:

Fundoscopy as part of dilated eye examination was done on 211 patients. The results showed that 78 had cataract, 38 had background retinopathy, 16 had pre-proliferative retinopathy, 2 had proliferative retinopathy and 11 were documented having abnormal changes. Four patients were referred to an ophthalmologist for the examination.

Table 27: Percentage distribution of Fundoscopy according to gender in T2DM subjects

Fundoscopy	Gender		Total
	Male	Female	
Normal	73 (70.9%)	71 (63.4%)	144 (67.0%)
Abnormal	7 (6.8%)	4 (3.6%)	11 (5.1%)
Back Ground Retinopathy	13 (12.6%)	25 (22.3%)	38 (17.7%)
Proliferative Retinopathy	1 (1.0%)	1 (0.9%)	2 (0.9%)
Pre-Proliferative Retinopathy	8 (7.8%)	8 (7.1%)	16 (7.4%)
Referred	1 (1.0%)	3 (2.7%)	4 (1.9%)
Total	103	112	215

Table 28: Percentage distribution of Fundoscopy according to age group in T2DM subjects

Fundoscopy	Age Group			
	20-40 years	41-60 years	≥61 years	Total
Normal	26 76.4%	96 48.7%	21 34.4%	143 49.0%
Abnormal	3 8.9%	7 3.6%	1 1.6%	11 3.8%
Back Ground Retinopathy	2 5.8%	27 13.7%	9 14.7%	38 13.0%
Proliferative Retinopathy	0 .0%	2 1.0%	0 .0%	2 0.7%
Pre-Proliferative Retinopathy	0 .0%	10 5.1%	6 10%	16 5.4%
Referred	0 .0%	4 2.0%	0 .0%	4 1.4%
Cataract	3 8.9%	51 25.9%	24 39.3%	78 26.7%
Total	34 100.0%	197 100.0%	61 100.0%	292 100.0%

3.1.16 Lower Leg Examination:

Fourteen patients (10 men and 4 women) had diabetic foot ulcer. Interestingly, 13 of these foot ulcers seen on the right foot. A total of 317 patients examined for popliteal pulses; 325 for posterior tibialis and dorsalis pedis. Sense of vibration recorded in 296 and touch sensation in 297 patients. Knee jerk reflexes recorded in 294 and 297 were examined for ankle jerk reflexes.

3.1.17 Diabetes Management:

The management of patients with type 2 diabetes was complex and nearly all patients required pharmacological therapy. Of the 691 patients, 41% were on Aspirin; 20.3% on ACE inhibitors; 27% on anti-hypertensive; 15.6% on statin and 22% on insulin which was injected twice a day. While 17 patients were counseled for insulin therapy and 2 were advised to start it. Though 75 patients had LDL value of >130 mg/dl of these only 13 were prescribed statin. BP $\geq 140/90$ mm Hg was seen in 19.7% patients and they were prescribed anti- hypertensive medicines. While 23% patients who also had BP $\geq 140/90$ mm Hg but they were not prescribed any anti-hypertensive medicine. Patients who were taking antihypertensive medications; of these, 10.6% had a BP level of $\leq 140/90$ mm Hg, and only 5% had a BP level of $\leq 130/80$ mm Hg. A total of 15.6% patients were on lipid-lowering medications. In patients taking lipid-lowering medication, the total cholesterol level averaged 208.12 mg/dl (5.33 mmol/l) 208.12mg/dl and the triglyceride level averaged 266.12 mg/dl (3 mmol/l). The HDL cholesterol level averaged 40.90 mg/dl (1.04 mmol/l) and the LDL cholesterol level averaged 128.07 mg/dl (3.28 mmol/l). In patients not taking lipid-lowering medications, the total cholesterol level averaged 191.24 mg/dl (4.9 mmol/l) and the triglyceride level averaged 215.88 mg/dl (2.42 mmol/l). The HDL cholesterol level averaged 38.86 mg/dl (1 mmol/l), and the LDL cholesterol level averaged 115.78 mg/dl (2.96 mmol/l).

Table 29: Chronic complications and its management in T2DM subjects

Variables	Documented for:		Found to be on/suffering from:	
	N	%	N	%
Management:				
Aspirin	691	100.0	283	41.0
ACE	616	89.1	125	20.3
Anti HTN	593	86.0	160	27.0
Statin	332	48.1	52	15.6
Insulin	691	100.0	152	22.0
Complications:				
Retinopathy	224	32.4	70	31.3
Nephropathy	159	23.0	36	22.6
Hypertension	593	86.0	349	59.0
Hyperlipidemia	326	47.2	276	84.7
CVD	607	87.8	39	6.4
Stroke	624	90.3	01	0.2
Peripheral Neuropathy	631	91.3	60	18.6
Peripheral Vascular Insufficiency	317	46.0	46	14.5

3.1.18 Diabetes Complications:

Many patients with type 2 diabetes had complications from their diabetes as screened during their first visit to the PDCs. Dyslipidemia was seen in 84.7%. Microvascular complications like retinopathy were seen in 31.3%, nephropathy in 22.6% and peripheral neuropathy in 18.6%. Diabetic foot ulcer was seen in 2% patients. Macrovascular complications like hypertension were seen in 59%, cardiovascular disease in 6.4% and stroke in 0.2% patients. Peripheral vascular insufficiency found in 14.5% patients.

Among the genders our data shows that more men had diabetic foot ulcer, nephropathy, CVD, stroke, peripheral neuropathy and peripheral vascular insufficiency as compared to women. Retinopathy and hypertension as chronic complications were seen more in women. Dyslipidemia was found almost equally in both genders.

Table 30: Age and various diabetes complications in T2DM subjects

Age Group (Years)	Retino n (%)	Nephro n (%)	Neuro n (%)	*CVD n (%)	**PVI n (%)
20 – 40	5 (7.1)	2 (5.6)	8 (13.6)	-	2 (4.3)
41 – 60	49 (70.0)	19 (52.8)	44 (74.6)	25 (64.1)	29 (63.0)
≥ 61	16 (22.9)	15 (41.7)	7 (11.9)	14 (35.9)	15 (32.6)
Total	70 (31.2)	36 (22.6)	59 (18.5)	39 (6.5)	46 (14.6)

*CVD = Cardiovascular disease

**PVI = Peripheral vascular insufficiency

Most of the diabetes complications were seen in patients between 41-60 years of age.

Table 31: Duration of diabetes and various diabetes complications in T2DM subjects

Duration of DM (Years)	Retino n (%)	Nephro n (%)	Neuro n (%)	*CVD n (%)	**PVI n (%)
<2	11 (15.7)	3 (8.3)	7 (11.9)	4 (10.3)	3 (6.5)
2 -10	33 (47.1)	20 (55.6)	38 (64.4)	16 (41)	22 (47.8)
> 10	26 (37.1)	13 (36.1)	14 (23.7)	19 (48.7)	21 (45.7)
Total	70 (31.5)	36 (22.6)	59 (18.6)	39 (6.7)	46 (14.9)

*CVD = Cardiovascular disease

**PVI = Peripheral vascular insufficiency

Patients who had between 2-10 years duration of diabetes the chronic complications were higher in them. Those patients with >10 years of diabetes in them CVD, retinopathy and nephropathy were prominent.

Table 32: HbA1c and various diabetes complications in T2DM subjects

HbA1c (%)	Retino n (%)	Nephro n (%)	Neuro n (%)	*CVD n (%)	**PVI n (%)
≤ 7	3 (5.6)	3 (9.1)	4 (9.5)	3 (13.0)	2 (6.1)
>7 and ≤ 8	8 (14.8)	3 (9.1)	8 (19.0)	3 (13.0)	5 (15.2)
> 8 and ≤9	14 (25.9)	11 (33.3)	13 (31.0)	7 (30.4)	10 (30.3)
> 9	29 (53.7)	16 (48.5)	17 (40.5)	10 (43.5)	16 (48.5)
Total	54 (30.9)	33 (22.0)	42 (17.8)	23 (8.2)	33 (17.7)

*CVD = Cardiovascular disease

**PVI = Peripheral vascular insufficiency

Those with HbA1c ≤ 7%, 3 had retinopathy, 3 had nephropathy, 4 had peripheral neuropathy, 3 had CVD and 2 had PVI.

HbA1c >9% seen in 29 with retinopathy, 16 with nephropathy, 17 with peripheral neuropathy, 10 with CVD and 16 with PVI. This shows that most patients suffering from diabetes complications had poor glycemic control.

Table 33 (a): Percentage distribution Systolic BP, diastolic BP and various diabetes complications in T2DM subjects

SBP (mmHg)	Retino n (%)	Nephro n (%)	Neuro n (%)	*CVD n (%)	**PVI n (%)
≤130	24 (34.8)	18 (50.0)	30 (52.6)	15 (41.7)	14 (31.8)
>130	45 (65.2)	18 (50.0)	27 (47.4)	21 (58.3)	30 (68.2)

*CVD = Cardiovascular disease

**PVI = Peripheral vascular insufficiency

Table 33 (b): Percentage distribution of hypertensive DBP and various diabetes complications in T2DM subjects

DBP (mmHg)	Retino n (%)	Nephro n (%)	Neuro n (%)	*CVD n (%)	**PVI n (%)
≤80	24 (34.8)	17 (47.2)	32 (56.1)	13 (36.1)	18 (40.9)
>80	45 (65.2)	19 (52.8)	25 (43.9)	23 (63.9)	26 (59.1)

*CVD = Cardiovascular disease

**PVI = Peripheral vascular insufficiency

Forty five patients (65.2%) having retinopathy had DBP >80 mm Hg followed by 23 (63.9%) who had CVD.

Table 34: Percentage distribution of age group and diabetes management in T2DM subjects

Variable	20-40 years	41-60 years	≥61 years	Total
Aspirin	55 19.9%	181 65.3%	41 14.8%	227 40.8%
ACE	15 12.3%	74 60.7%	33 27.0%	122 20.1%
Anti-HTN	16 10.1%	103 65.2%	39 24.7%	158 27.1%
Statin	9 17.6%	31 60.8	11 21.6%	51 15.5%
Insulin	26 17.4%	97 65.1%	26 17.4%	149 21.9%

Table 35: Percentage distribution of duration of Diabetes and diabetes management in T2DM subjects

Variable	<2 years	2-10 years	>10 years	Total
Aspirin	70 25.3%	144 52.0%	63 22.7%	277 41.7%
ACE	28 22.6%	64 51.6%	32 25.8%	124 20.6%
Anti-HTN	33 20.9%	88 55.7%	37 23.4%	158 27.2%
Statin	15 29.4%	25 49.0%	11 21.6%	51 15.6%
Insulin	13 8.7%	65 43.6%	71 47.7%	149 22.4%

Table 36: Percentage distribution of BMI groups and diabetes management in T2DM subjects

Variable	Under weight <18.5 kg/m²	Normal 18.5-22.9 kg/m²	Over weight 23-25 kg/m²	Obese >25 kg/m²	Total
Aspirin	0 0%	42 7.2%	50 8.5%	144 24.6%	236 40.3%
ACE	2 0.4%	14 2.7%	24 4.6%	70 13.3%	110 21.2%
Anti-HTN	0 0%	15 3.0%	30 6.0%	87 17.4%	132 26.5%
Statin	1 0.3%	6 2.1%	9 3.1%	28 9.7%	44 15.2%
Insulin	3 0.5%	28 4.8%	29 5.0%	71 12.1%	131 22.4%

3.2 Findings of Frequency of Chronic Complications:

The frequency of diabetes complications, overall and between the genders is shown in Table A. The most frequently occurring metabolic abnormality was high HbA1c (89.9%), followed by hyperglycemia on the basis of FBG (88.3%), hypertriglyceridemia (70.0%) and obesity (60.5%).

Table A: Frequency of Chronic Complications according to gender in all PDCs

Metabolic variables	Overall %	Male %	Female %	Sign. P-Value
Hyperglycemia on the basis of FBG (>120 mg/dl)	88.3	88.6	88.0	ns*
HbA1c >7%	89.9	89.2	90.7	ns
≥150 mg/dl (Hypertriglyceridemia)	70.0	76.2	64.0	0.022
>200mg/dl (Hypercholesterolemia)	40.4	42.9	38.0	ns
High LDL >100 mg/dl	68.1	71.4	65.2	ns
Low HDL <40 mg/dl	48.8	55.3	52.7	0.071
Obesity	60.5	53.8	67.2	0.008
Microvascular complications				
Retinopathy	31.3	29.4	32.8	ns
Nephropathy	22.6	28.6	16	0.059
Peripheral Neuropathy	18.6	21.6	16	ns
Diabetic Foot Ulcer	2.0	3.0	1.1	0.175
Macrovascular complications				
Hypertension	59.0	56.2	62.0	ns
Coronary Artery Disease	6.4	7.3	5.6	ns
Stroke	0.2	0.3	-	ns
Peripheral Vascular Insufficiency (PVI)	14.5	15.6	13.5	ns

Within gender

ns* = not significant

Among microvascular complications retinopathy was 31.3%, peripheral neuropathy was 18.6% and nephropathy 22.6%. Among macrovascular complication half of the subjects (59.0%) were hypertensive. Among females frequency of obesity ($p=0.008$) was significantly higher and among males frequency of hypertriglyceridemia ($p=0.022$) was significantly higher.

The frequency of diabetes complication according to age showed that retinopathy ($p=0.014$), hypertension ($p=0.001$), cardiovascular disease (CVD) ($p=0.010$), and peripheral vascular insufficiency (PVI) ($p=0.033$), was significantly higher among the older group i.e. >45 years, shown below in Table B.

The frequency of diabetes complication according to duration of diabetes showed that retinopathy ($p=0.002$), diabetic foot ulcer ($p=0.004$), coronary artery disease ($p=0.000$) and PVI ($p=0.000$) was significantly higher among those with longer duration of diabetes i.e. > 10 years, shown below in Table C.

Table B: Frequency of various chronic complications according to age.

Chronic complications	Age Group		
	≤45 yrs %	>45 yrs %	p value chi-sq test
Metabolic variables			
Hyperglycemia on the basis of FBG (>120 mg/dl)	89.8	87.6	ns*
HbA1c >7%	91.3	89.5	ns
≥150 mg/dl (Hypertriglyceridemia)	67.1	70.6	ns
>200mg/dl (Hypercholesterolemia)	39.5	41.3	ns
High LDL >100 mg/dl	69.0	68.5	ns
Low HDL <40	42.3	50.9	ns
Obesity (>25kg/m ²)	61.9	60.5	ns
Microvascular Complications			
Retinopathy	15.9	35.0	0.014
Nephropathy	13.8	24.6	ns
Peripheral Neuropathy	17.6	18.8	ns
Diabetic Foot Ulcer	2.4	1.8	ns
Macrovascular Complications			
Hypertension	43.5	59.2	0.001
Coronary Artery Disease	2.0	8.0	0.010
Stroke	-	0.2	ns
Peripheral Vascular Insufficiency	6.2	16.8	0.033

Within age group

ns* = Not significant

Table C: Frequency of various chronic complications according to duration of T2DM in all PDCs

Chronic complications Duration of Diabetes

Metabolic variables	≤10 yrs %	>10 yrs %	P-value Chi-sq test
Hyperglycemia on the basis of FBG (>120 mg/dl)	88.7	85.7	ns*
HbA1c >7%	89.5	90.9	ns
≥150 mg/dl (Hypertriglyceridemia)	71.6	66.2	ns
>200mg/dl (Hypercholesterolemia)	39.7	43.4	ns
High LDL >100 mg/dl	67.9	68.1	ns
Low HDL <40	45.7	58.6	0.051
Obesity (>25kg/m ²)	61.9	56.2	ns
Microvascular Complications			
Retinopathy	26	49.1	0.002
Nephropathy	19.2	33.3	0.066
Peripheral Neuropathy	18.5	18.7	ns
Diabetic Foot Ulcer	1.2	5.1	0.004
Macrovascular Complications			
Hypertension	53.1	62.1	0.068
Coronary Artery Disease	4.5	13.9	0.000
Stroke	-	0.7	ns
Peripheral Vascular Insufficiency	89.4	70.8	0.000

Within duration of DM

ns* = Not significant

CHAPTER FOUR

DISCUSSION

4.1 METHODOLOGICAL DISCUSSION

4.2 Discussion on the Findings of the Study

Results of our study indicate that family physicians are not adequately following the 2004 ADA standards for comprehensive disease management of their patients with diabetes. This outcome is seen despite widespread awareness about diabetes and its preventive management by diabetologists at different peripheral diabetic clinics. We do not know if other diabetes clinics in the region have annual auditing of their medical records to assess the performance of the medical practitioners and their respective clinics.

4.2.1 Compliance with ADA guidelines:

Our study provides evidence that ADA guidelines were not been completely implemented in the four PDCs run by trained family physicians called diabetologists. The comorbidities and diabetes complications were frequent and patients with type 2 diabetes had poor glycemic control. Complex treatment regimens were necessary. In addition to metabolic outcomes, process measures are also important in good diabetes care. Screening rates in the patients with type 2 diabetes were not good, especially for eye examinations, microalbuminuria and lower extremities examination. Screening for BMI, blood pressure and lipid profiles were relatively better. All patients were not tested for diabetes complications during the study period and urine albumin screening was documented for only 25% of the patients.

We found that screening of various metabolic measures at PDC1 was closer in compliance with ADA guidelines than the other three PDCs. However, none of the PDCs had complete documented medical records as several parameters were found missing in all. Apparent failure to meet ADA guidelines may reflect the true limitations of our practice, but analysis was based largely on data recorded by hand in patient medical records and may have underestimated actual performance.

In our study 18.4% subjects between 20-40 years of age had type 2 diabetes. In Asian population this trend of occurrence of type 2 diabetes at a younger age is comparable to other studies. Mean age of males and females was younger as compared to Caucasians (44). The high prevalence of diabetes (66.1%) in the 41-60 age group meant that the majority of diabetics were suffering from the disease in their most productive years of life (53). Mean age of the diabetics in our study was 51.4 ± 11.45 years for males and 50.5 ± 9.33 for females. The fact that 60% subjects gave a positive family history of diabetes indicates a strong familial influence of the disease in our population. However, this could also be due to life style changes and inadequate physical activities among the population.

We know that obesity is taken as a risk factor for diabetes and cardiovascular disease (54). In February 2000, the WHO Regional Office for the Western Pacific, the International Association for the Study of Obesity, and the International Obesity Task published provisional recommendations for adults in Asia-Pacific as overweight at BMI $>23\text{kg/m}^2$ and obesity at BMI $>25\text{kg/m}^2$ (49). According to the new recommendations 60.5% of our diabetic subjects were obese with a BMI $>25\text{ kg/m}^2$ and among these (67.2%) females were more obese than their male counterpart. Another study in our region has shown a similar pattern of obesity, hypertension and dyslipidemia among rural population of Pakistan (55).

4.2.2 Glycemic control (HbA1c)

Information about overall glycemic control in type 2 diabetic in Pakistan is lacking. Recommended ADA guidelines for glycemic control is HbA1c $<7\%$ and pre-prandial plasma glucose (or FBG) 80-120 mg/dl. In our study, ADA recommendations met in 40 (10.8%) patients who had FBG between 80 -120 mg/dl and 10.15% had HbA1c of $\leq 7\%$. HbA1c of >7 and $\leq 8\%$ in 14.6%, and $>8\%$ in 75.3% patients showed that the diabetic population coming to these PDCs had poor glycemic control of their diabetes. The

ADA recommendations for assessment of glycemic control are: Perform HbA1c at least two times/year in patients who are meeting treatment goals, and perform HbA1c quarterly in patients not meeting glycemic goals. Since we reviewed the medical records of those subjects who came to the PDCs at their first visit, therefore, we did not assess the above ADA recommendations.

The mean values of HbA1c 9.13% found in our study are slightly higher than those observed in Bangladesh (HbA1c 8.01%) (54) and is closer to that found in India (HbA1c 9.3%) (56). About three-fourth (90%) of the subjects had poor glycemic control on their first visit to the PDCs and 51.7% of them had diabetes between 2-10 years. This is indicative of early high tendency of diabetic complications due to poor glycemic control. In short, HbA1c values indicated that patients coming to the PDCs did not have their diabetes under optimal control.

4.2.3 Lipid profiles

Dyslipidemia is prevalent in diabetic patients and increases risk for atherosclerotic vascular disease (57, 58, 59). Dyslipidemia increases risk for atherosclerotic vascular disease in diabetic patients, and effective management has been shown to reduce secondary vascular events (58, 59, 60). ADA guidelines recommend a LDL level ≤ 100 mg/dl. In our study, only 32% patients had documented LDL levels ≤ 100 mg/dl. Between 41-60 years of age 71.3% patients had TC ≥ 200 mg/dl and 75% had LDL > 130 mg/dl. Significantly higher triglycerides and low HDL which is typical of diabetes dyslipidemia were also seen in a study in India (53). We know that low HDL cholesterol is an independent risk factor for chronic heart disease. The overall high percentage (43.3%) of low HDL in our study shows similar evident of low HDL prevalence in Pakistani population in another study (55). Furthermore, only 15.6% patients with a diagnosis of dyslipidemia were at ADA goals. Though 75 patients had LDL value of > 130 mg/dl of these only 17.3% were prescribed statin. This showed that

the comorbid conditions of dyslipidemia were not managed according to the ADA guidelines.

4.2.4 Hypertension

On the basis of ADA 2004 recommendations, blood pressure goal of $\leq 130/80$ was documented in 44.7% (265) patients. In our study 61.2% (363) of the patients had SBP in desired range and 49% (291) had DBP in desired range. Only 03 patients of the total sample of 691 met the recommended ADA treatment values of HbA1c level $\leq 7\%$, a blood pressure $\leq 130/80$ mmHg and an LDL level ≤ 100 mg/dl. BP $>130/80$ of mm Hg was found in 55.3% patients (145 men and 183 women). Blood pressure levels in the patients averaged 138/86 mmHg. Research has shown that lowering blood pressure to a mean of 144/82 mm Hg in hypertensive diabetic patients significantly reduced complications of macrovascular and microvascular disease and diabetes-related deaths (56, 61, 58, 59).

Although the majority of patients in the study had blood pressure measured, of the total sample only 27% of patients were taking antihypertensive medications and met criteria for control. In the patients with a diagnosis of hypertension, only 19.7% were treated to the ADA goal. Family physicians were better at documenting blood pressure than lipid levels.

4.2.5 Management of T2DM

Our study showed that management of the comorbid conditions for hypertension and dyslipidemia was overall suboptimal but better compared to other diabetes management at the PDCs. ADA recommends that urine be tested annually for presence of Microalbuminuria. During their first visit, in view of this only 25% patients were screened for microalbuminuria. ADA recommends that dilated eye examination (fundoscopy) be performed shortly after diagnosis of diabetes and then annually. In our study 31% patients had eye examination at first visit.

Since we did not audit the medical records of these patients for annual reviews; we may assume that some of these patients had their annual screening tests and examinations during the annual review visits. Of the 691 patients, 41% were on Aspirin; 20.3% on ACE inhibitors; 27% on anti-hypertensive; 15.6% on Statin and 22% on insulin injected twice a day. A high prescription rate of insulin was expected and this showed that the family physicians had implemented intensive management for good glycemic control to improve diabetes care in the community.

It has been recommended that medical management to decrease cardiovascular risk should start when type 2 diabetes mellitus is diagnosed (62, 63). At the very least, medications proven to reduce cardiovascular risk should be prescribed for patients with diabetes and established atherosclerotic disease (64). In addition to smoking cessation and control of blood pressure, strategies proven to reduce cardiovascular risk in patients with diabetes and established atherosclerotic disease include therapy with antiplatelet agents, statins and angiotensin-converting enzyme (ACE) inhibitors (62).

Only 74 patients between 41-60 years of age were on ACE therapy and remaining 331 patients were not on ACE medications. While ACE therapy prescribed to 62 out of 240 patients with high CVD risk and 104 out of 328 patients with hypertension. We found that the use of all 3 types of agents (antiplatelet agents, ACE inhibitors and statins) proven to reduce cardiovascular risk was low in our study. This is indicative of poor compliance with ADA guidelines.

Adhering to ADA recommendation for anti-platelet therapy, Acetylsalicylic acid i.e. aspirin was prescribed to patients only >21 years of age. In our study for primary prevention according to ADA guidelines, aspirin therapy in type 2 diabetes patients with increased CV risk was prescribed to:

- ◆ Age > 40 (181 patients)
- ◆ Family history of CVD (not documented in the medical records)
- ◆ Hypertension (155 patients)
- ◆ Smoking/tobacco consumption (21 patients)

♦ Dyslipidemia (148 patients)

♦ Albuminuria (51 Patients)

A survey of 104 physicians including 8 physicians with special interest in diabetes was conducted in Karachi. The aim was to assess current physician knowledge and practice of optimal and acceptable diabetes care. That study also showed suboptimal standard of diabetes care by the healthcare providers. (65)

Although barriers to successful management by the family physicians is not known but could include lack of knowledge of current recommendations, patient compliance issues including medication cost and side effects, and lack of available diabetes educators (66).

4.2.6 Chronic Complications:

Among the individual PDCs, 74.1% patients were screened for HbA1c at PDC2 and 32% at PDC3. Poor glycemic control of patients with a mean value of HbA1c >9.5% was found in PDC4. Blood pressure screening of patients showed BP >130/80 mmHg more in PDC1 and less in PDC4. Prevalence of chronic complications found in screened patients is as follows: 40% retinopathy seen in PDC3; 71.4% nephropathy in PDC3; 64.3% hypertension in PDC1; 91.4% dyslipidemia in PDC1; 10.7% CVD in PDC4, 0.5% stroke in PDC2; 20% peripheral neuropathy in PDC1 and 15% peripheral vascular insufficiency in PDC1.

Among the macrovascular complications in our study, overall rates of CVD were 6.4%, and stroke 0.16%. This pattern was similar to that reported from India (CVD was 11.4% and Stroke 0.9%) (56). A similar study conducted in Karachi reported higher rates of chronic complication than in our study (hypertension 46%, neuropathy 49% and CVD 28%) (67). In our study, the prevalence of peripheral vascular insufficiency was 14.5% and 2% patients had diabetic foot ulcers. This could be related to the social and cultural behavior of these subjects, particularly bare-foot walking. Furthermore, peripheral neuropathy found in 18.6% could aggravate the risk of injuries and foot ulceration. Nephropathy was seen

in 22.6% of patients. In our study the prevalence of retinopathy was 31.3% other studies too have shown higher prevalence (53, 68, 69). The comorbidities are preventable, with evidence documenting that a 1% reduction in HbA1c can reduce the risk of myocardial infarction (MI) by 16% (70); a 10 mmHg reduction in systolic BP could decrease all-cause mortality, MI, stroke and microvascular complications by 18%, 21%, 44% and 37%, respectively (71); and improving lipid profile can reduce the risk for coronary artery disease by 22%-55% (72)

4.2.7 Frequency of chronic complications:

This study also showed the pattern of diabetic complications and its associations with gender, age and duration of diabetes among type 2 diabetic subjects in peripheral diabetes clinics.

Obesity (67.2%), hypertension (53.2%) and retinopathy found to be higher in females while microvascular complications like nephropathy, peripheral neuropathy, and diabetic foot ulcers were more prevalent in males. Macrovascular complications like CVD and peripheral vascular insufficiency were also more in males than in females.

Frequency of obesity and hyperlipidemia did not increase with age or duration of diabetes suggesting that for a large proportion of subjects these disorders could have appeared before the onset of diabetes i.e. during the impaired glucose period. The frequency of hypertension increased with age in those >45 years of age and 59.2% of these subjects were hypertensive. This close association of diabetes and hypertension is a well known phenomenon. (54, 56, 69, 63)

In our study, the frequency of retinopathy, nephropathy, CVD and peripheral vascular insufficiency increased with age and duration of diabetes. This was also observed in other (73) studies in the Asian and Middle-East region. (74, 75) No difference in HbA1c level was evident based on gender, age and duration of diabetes.

4.3 METHODOLOGICAL CONSIDERATION

4.3.1 Study Design

In Pakistan more than 10% of the adult population suffers from diabetes. (76) The major diabetic complications include retinopathy, chronic heart disease, nephropathy, neuropathy, stroke, peripheral vascular disease and diabetic foot ulcer. Many of these complications, if not prevented and left untreated, can be fatal. All have the potential to reduce the quality of life of people with diabetes and their families. We also know that T2DM is a major risk factor for CVD and proper aggressive early treatment options can reduce this risk in such patients (77). It is well recognized that successful management of T2DM requires strict control of glycemia as well as of risk factors to prevent disease progression and many micro and macro-vascular complications (78, 79). Therefore, managing such type 2 diabetes patients is a challenge that trained health professionals are required to deal with in their specialized medical field. Hence great responsibility lies with the trained health professionals to follow the diabetic management of their patients in a systemic and recommended manner to delay or prevent serious macro and microvascular complications. This in return can help to reduce the economic and emotional burden of diabetes and morbidity and mortality among the population.

Keeping these views in our mind, we designed a study to learn the compliance of ADA guidelines by family physicians at their clinics. We also wanted to know the quality of diabetes care given and prevalence of chronic complications in type 2 diabetics at the PDCs.

4.3.2 Retrospective Cross sectional study

In our retrospective study we audited medical records of patients for research. Six hundred and ninety-one medical records of registered type 2 diabetics from four PDCs were audited. Such data collection can enable vast numbers of people to be entered into a study prospectively or retrospectively. They can be used to construct a cohort, to produce a

sample for a cross sectional study, or to identify people with certain conditions or outcomes and produce a sample for a case controlled study (80). As a group cross sectional studies are descriptive studies that can be used for testing hypotheses. They are used in surveys of various types and for measuring prevalence. Prevalence equals the number of cases in a population at a given point in time. In cross sectional studies all observations are made on a single occasion. Prevalence is vitally important to the clinician because it influences considerably the likelihood of any particular diagnosis and the predictive value of any investigation. They are usually carried out on the general population and disease can be classified by personal characteristics like age, sex, race, education, socioeconomic status and time or place. Cross sectional studies are also useful for describing the clinical spectrum of a disease, e.g., diabetes maybe used to study proportion who has retinal, renal or cardiovascular complications. Cross sectional studies look at outcome and exposure at the same time.

The advantage of such studies is that subjects are neither deliberately exposed, treated, or not treated and hence there are seldom ethical difficulties. Only one group is used, data are collected only once and multiple outcomes can be studied; thus this type of study is relatively cheap. Many cross sectional studies are done using questionnaires. Alternatively each of the subjects may be interviewed. A census is another example of a cross sectional study.

Cross sectional studies (Key points)

- Cross sectional studies can determine prevalence
- Are relatively quick and cheap
- Fewer resources required
- Indicate associations (81)

During a retrospective cross sectional study design a number of problems may arise that may invalidate the results unless they are properly handled.

4.3.3 Strength of the Study

Our study was a primary healthcare based study focusing on patients coming to peripheral diabetes clinics in different townships of Karachi. The clinics provided easiest selection of samples with remote chances of misdiagnosis with other non communicable diseases and this gives validity of diagnosis. There was relative homogeneity of the sample in terms of access to health care. Because the data were recorded in medical records, use of this information eliminated the potential for recall bias and increased the reliability of the data.

4.3.4 Weakness of the Study

The study has several limitations. We consider that our conclusions are based on the auditing of the documented medical records of T2DM coming to the PDCs. However, the FPs may have been more thorough in their examinations and management than is noted in the medical records of the patients. It is to be remembered that documentation is increasingly considered a valid substitute for what was actually asked or done. At the PDCs physicians were often reminded and encouraged to keep accurate and updated medical notes. In the past, medical records from PDCs were not audited and the performance of the physicians and their clinics not evaluated.

Information collected such as laboratory test results, blood pressure, monofilament examination, and presence of comorbid conditions should be complete and reliable. There is a limitation to the reliability of results of review of medical records when these records have incomplete documentation. Other limitations of our study included its retrospective nature and we agree that a prospective manner of data collection would have given strength to reliability of the findings. In some cases,

complications noted in the problem list could not be confirmed with the limited data available. Data on level of income and education were not collected.

If a sample is used, it is essential to ensure that the subjects included in the sample are representative of the population being investigated. The T2DM population targeted during our study was not representative of the whole population as it included those patients who could afford treatment at these private PDCs. Those type 2 diabetics who cannot financially afford treatment either go to government health facilities, charitable health clinics or to other local healers in their locality. Our results maybe population specific and biased toward those patients who had resources that permitted more visits per year. This is reflected as during the study period, 492 (71.2%) visited the PDCs only once and 199 (28.8%) visited more than once. Out of 691 patients only 8 had their annual review and those findings at annual review were not included in the study.

Another limitation is the lack of data on the prevalence of hypoglycemia. Although we believe that severe hypoglycemia is uncommon in our patients, many patients using sulfonylureas or insulin report intermittent glucose levels of 54 mg/dl (3 mmol/l). We found one patient had FBG 60 mg/dl but it was not mentioned whether symptoms of hypoglycemia were present. Waist-Hip ratio was not measured and is not clinically common in medical practice of family physicians. Some PDCs were better equipped with basic health facilities than others – this may have given them undue advantage over their individual performance. This lack of infrastructure can be attributable to no lower leg examinations performed at two PDCs. No diabetes education or dietary counseling and nor self-monitoring of blood glucose (SMBG) was recorded. Furthermore, Ultrasound Doppler test and Ankle Brachial Index (ABI) are performed to help in diagnosis of PVD and these tests were not done to assess PVD.

4.4 CONCLUSIONS

Our data shows that most medical records of the patients that visited the different PDCs were inadequately filled and lacked proper documentation. Screening evaluations recommended by ADA guidelines for early detection of diabetes complications were suboptimal in the PDCs.

In our part of the world, we generally have a culture of not documenting medical information as required in medical records or forms in the healthcare centers. Poor record maintenance shown in our study may signify the importance of periodic auditing of medical records and forms at healthcare centers in order to assess quality of diabetes primary care given to the patients.

The study showed poor glycemic control despite a younger population and shorter duration of diabetes. Fewer patients were screened for detection of diabetes management and chronic complications. Many patients screened for diabetes complications were found to have more than one complication. The high prevalence of diabetes complications can contribute to economic burden of the disease on the patients and their families.

We found that obesity, poor glycemic, blood pressure and lipid control can be contributing causes to the increase frequency of chronic diabetes complications among our patients.

Since complications are already present at diagnosis, this indicates late diagnosis.

In short, a wide gap seems to exist between effective diabetes management practices and their implementation. The study strongly suggests the need for developing interventions targeted at patients, healthcare providers and other stakeholders for improving the quality of diabetes care.

The quality of diabetes care generally imparted was suboptimal and based on the findings of our study we made the following recommendations:

4.5 RECOMMENDATIONS

1. The primary management goals of diabetes are to reduce the prevalence or worsening of chronic complications of diabetes. In this regard, frequency of testing, especially for patients with suboptimal control, needs improvement.
2. Strategies to improve family physicians compliance with documenting screening and management of dyslipidemia and hypertension in diabetic patients are needed.
3. We suggest that inexpensive quality care should be provided to the patients who largely come from low resource and underserved communities. This can be done one way by giving discount rates for laboratory tests and medications.
4. Our findings suggest a need for interventions to improve healthcare provider compliance with ADA guidelines. In addition, improved patient access to diabetic educators could benefit family physicians.
5. Interventions targeted at primary care providers' office staff may be more fruitful than those targeted solely at physicians. There is also a need for use of non-physician providers to perform some examinations like foot inspection and use of protocols.
6. Public health resources should be focused on identifying ways to improve the efficacy of patient-physician partnerships aimed at achieving practice recommendations.
7. Further research is needed to determine barriers to successful diabetes management by healthcare providers so that alternative strategies can be implemented and tested.

4.6 FUTURE RESEARCH IMPLICATIONS

1. We need large scale and cost-effective prevention programs to improve primary diabetes care in low resource and underserved communities as well as to reduce the cost of diabetes in Pakistan. One way of achieving this can be through international collaboration with the aims at improving health care delivery through setting up diabetes clinics and training of health care providers.

2. Similar projects like the one between World Diabetes Foundation (WDF) and BIDE are needed nationally in order to improve primary healthcare delivery. Under this project more than 75 doctors will participate in a 1-year specialized training course in diabetes and its management. After the course each of the trained doctors is expected to start a peripheral diabetes clinic (82). The project duration is from Nov 2007 to Nov 2010. During this three years period a prospective study can be done to learn the adherence of ADA recommended guidelines at the newly established PDCs.

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APPENDIX